

AN OFFICIAL PUBLICATION OF THE SOCIETY OF HOSPITAL MEDICINE

### **Hospital readmissions** penalties now in 5th year

Some question whether hospitals should be held accountable for readmissions

#### By Larry Beresford

ith the Hospital Readmissions Reduction Program (HRRP) in its 5th year, what has been the impact on hospitals and on hospitalists? First, a lot of penalties have been paid by hospitals. According to an analysis by Kaiser Health News,<sup>1</sup> the Centers for Medicare & Medicaid Services will withhold \$528 million from 2,597 hospitals in the current fiscal year, Oct. 1, 2016, to Sept. 30, 2017, for readmissions for six diagnoses that occurred between July 2012 and June 2015. The number of penalized hospitals is down slightly from 2,665 the year before, but the total annual withheld will go up by \$108 million.

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HRRP exacts Medicare payment penalties from hospitals that have rates of readmissions - within 30 days of discharge - that are higher than expected, based on national rates and the health of their patient population. The maximum penalty is now up to 3% of a

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#### THE PHYSICIAN **AS PATIENT**

Neha Sharma, DO

SEE PAGE 10



### How hospitalists can help reduce readmissions

Target discharge interventions for patients at high risk of readmission

#### By Karen Appold

ospital readmissions are frequent, harmful, and costly. Consider the fact that 18% of Medicare patients can expect to be readmitted within 30 days at a cost of more than \$17 billion.<sup>1</sup> Recent changes in health care policy aimed at reducing readmission have substantially increased attention to this major health care issue.<sup>2</sup>

The Affordable Care Act has mandated that the Centers for Medicare & Medicaid Services reduce payment to hospitals with higherthan-expected 30-day readmissions, with its Hospital Readmissions Reduction Program. This has driven rapid growth in the study of patients rehospitalized within 30 days of discharge.<sup>3</sup> So what are some strategies that have either been proven to reduce readmissions or show promise in doing so?

#### An ounce of prevention

In studying inpatient and outpatient physicians' perspectives regarding factors contributing to readmission,<sup>4</sup> Shoshana Herzig, MD, MPH, assistant professor of medicine, Harvard Medical School, Boston, and director of hospital medicine research, Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, and her colleagues identified some potential preventive strategies.

The most commonly endorsed strategy to prevent readmissions by both primary care physicians and hospitalists surveyed involved improving self-management plans at discharge. "This refers to actions such as provid-CONTINUED ON PAGE 20

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### HOSPITALIST MOVERS AND SHAKERS

#### By Matt Pesyna

**Robert Harrington, MD, SFHM,** recently was tabbed as chief medical officer of SurveyVitals, a health care analytics company specializing in digital patient-

experience surveys. Dr. Harrington has 20 years' experience, including CMO roles with Reliant Post– Acute Care Solutions and Locum Leaders, a hospitalist staffing firm.



With SurveyVitals, Dr. Harrington Dr. Harrington will

focus on client needs as the company seeks new ways to help patients provide feedback to providers. He also will support and direct the development of new features for Survey-Vitals.

Dr. Harrington is a senior fellow in Hospital Medicine and is past president and member of the board of directors with the Society of Hospital Medicine.

**David Northington, DO,** has been named the new chief medical officer at Stone County Hospital in Wiggins, Miss. The former hospitalist comes to Stone County after working as chief of staff and chief medical information officer at Memorial Hospital in Gulfport, Miss., where he was also medical director of the hospitalist program.

In addition to his new role, Dr. Northington will serve as medical director of the Woodland Village Nursing Center in Diamondhead, Miss., and the Stone County Nursing and Rehabilitation Center in Wiggins. Schuyler K. Geller, MD, has been recognized by Continental Who's Who as a Pinnacle Lifetime Member in the medical field. Dr. Geller works as a full-time hospitalist and a principal consultant for The CopperRidge Group, which provides guidance to patients in health, wellness, and fitness services and products.

In addition to his work at The Copper-Ridge Group, Dr. Geller is a member of Civil Vision International's board of directors. He has extensive civilian and military-based experience in the United States, Africa, the Middle East, and South Asia.

A physician leader in the U.S. Air Force, Dr. Geller earned White House Medical Unit commendations for planning and leading the surgical and intensive care unit teams to support President Clinton's trips to Vietnam and Africa in 2000.

Nikhil Sharma, MD, recently was selected by the International Association of Health-Care Professionals to be part of the Leading Physicians of the World. Dr. Sharma is a hospitalist serving at the Ochsner Health System in New Orleans.

Dr. Sharma, a member of the Southern Hospital Association and the Louisiana Medical Association, began his medical career in 2009 with a residency and fellowship at Ochsner, where he has remained ever since. He specializes in internal medicine and transplants.

**I. Carol Nwelue, MD,** a longtime hospitalist and the medical director of the Sparrow Medical Group Adult Hospitalist Service, recently received the Sparrow Physician Leadership Award. The award goes to an

CONTINUED ON FOLLOWING PAGE

### **BUSINESS MOVES**

The Mount Sinai Health System and The New Jewish Home, both based in New York City, have extended their relationship to improve care of hospitalized patients who require specialized post-acute or long-term care at a skilled nursing facility. Through the Mount Sinai-New Jewish Home Hospitalist Program, Mount Sinai hospitalists will be charged with providing a seamless transition to The New Jewish Home for patients who need nursing care.

This model will buoy communication and ensure the sharing of vital information between the two venues, reducing the risk of rehospitalization.

**Gryphon Investors,** based in San Francisco, recently announced it will acquire OB Hospitalist Group, one of the nation's leading providers of obstetric hospital medicine. The deal with OBHG's current partner, Ares Management, was finalized in late July.

OBHG, based out of Mauldin, S.C., has a national network of more than 550 OB hospitalists, covering more than 120 hospitals in 28 states. OBHG's hospitalist program features an obstetric emergency department, providing expectant mothers at partner hospitals with 24/7/365 access to medical care.

**Envision Healthcare,** based in Nashville, Tenn., and Greenwood Village, Colo., a provider of physician-led services and ambulatory surgery services, has acquired Milwaukee-based Infinity Healthcare. Infinity's group-physician practice includes more than 340 physicians and providers delivering emergency and hospital medicine, anesthesia, and radiology services.



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### Crossing the personal quality chasm: QI enthusiast to QI leader

QI expands a hospitalist's impact on patient and provider health



Dr. Jonathan Bae is associate chief medical officer for patient and clinical quality at Duke University Health System.

#### By Claudia Stahl

*Editor's Note:* This SHM series highlights the professional pathways of quality improvement (QI) leaders. This month features the story of Jonathan Bae, MD, SFHM, associate chief medical officer for patient and clinical quality at Duke University Health System, Durham, N.C.

ith a father and two sisters in medicine, Jonathan Bae was destined to become a physician – or something completely different, as he explains.

"Either outcome is common when you have a parent who is a doctor," said Dr. Bae, who has two siblings who chose a different career path. But while Dr. Bae's desire to be a clinician was set at an early age, his interest in quality improvement work came much later.

As associate chief medical officer for patient and clinical quality at Duke University Health System, Dr. Bae is helping to identify and outline the organization's collective quality strategy. "It's a tall order, but it's really exciting to have a seat at the table to figure out what we do as an overarching organization," Dr. Bae said.

Twelve years ago, Dr. Bae matched in Duke's Medicine-Pediatrics residency program because he wanted to be well equipped to treat patients across the age spectrum. Completing residency in 2009, Dr. Bae enjoyed providing clinical care as a hospitalist, but discovered that he also enjoyed teaching. To enhance his skills as a clinician educator, Dr. Bae enrolled in the Academic Hospitalist Academy, where the curriculum introduced him to quality improvement and patient safety, and some aspects of hospital administration. "Jeff Glasheen's talk on the drivers of medicine, and how to find your unique voice and identity ... brought together my interest in education and quality work," Dr. Bae recalled.

"I left the meeting energized with new information, and then the opportunity came up to lead a QI initiative here," he said. The project focused on improving care delivery to diabetic patients, specifically the completion of foot exams. "We saw our rates of screening go from less than 50% to greater than 80%," Dr. Bae said. "I found it to be extremely gratifying to be involved in implementing changes that could lead to care improvement for patients."

Once Dr. Bae made his interests in QI work known to colleagues and administrators, the projects came readily. Following his chief residency year, Dr. Bae remained with Duke Medicine Residency Program as an associate program director for QI, "which was a great platform for doing project work that aligned my interests in teaching and doing QI work," he said. In addition to developing a residency curriculum in QI, Dr. Bae initiated a program to incentivize GME trainees across the health system in performance metrics such as readmissions, patient satisfaction, hand hygiene, and safety event reporting. The outcomes, Dr. Bae said, "have had an improved quality and safety impact on our organization."

From there, Dr. Bae initiated multiple projects focused on reducing readmissions and mortality. Currently, he is standardizing the mortality review process across three hospitals in Duke's health system. Consistent methodology and language will allow for more accurate analysis and comparison of factors contributing to patient mortality in the system, Dr. Bae said, adding, "We have already learned a lot about care delivery and operations, and measures that can be taken to reduce gaps in care delivery and keep patients safe."

Looking back on the days when he only thought about providing care, Dr. Bae said, "my worldview has changed but my desire to change the world hasn't. I now do more quality work because I find it so gratifying. In the QI space, I'm affecting not one, but many people at a time."

He encourages hospitalists with similar interests to seek out colleagues and leaders – internal and external to their institutions – who will help them initiate and implement projects that feed their passions. Getting to know the QI basics is the simple part, Dr. Bae said.

"There's no magic behind PDSA cycles or models of improvement," he said. "It's the team and people you pull together that makes a project successful."

His current work centers on understanding and building health care provider resiliency at Duke. "I feel this ... is going to make a tremendous difference for our organization," Dr. Bae said. "The system should be designed to promote well-being, not just prevent burnout."

#### CONTINUED FROM PREVIOUS PAGE

emerging leader who provides outstanding work in areas such as safety, clinical or service excellence, research, teaching, publishing, teamwork, and innovation.

Dr. Nwelue completed the Sparrow Physician Leadership Academy program, earning recognition for innovation in leadership, as well as practice management.

**Laura Jin, MD,** recently was promoted to medical director for utilization management at the University of Maryland Shore Regional Health. In her new role, Dr. Jin will identify and facilitate the resolution of utilization issues; in so doing, she will serve as a consultant leader to the health care system, its physicians, its advance practice providers, and the care management team.

Dr. Jin will remain as a hospitalist at Digestive Health Associates while fulfilling the duties in her new position at Shore Regional. She will guide the center on issues such as compliance, level of care, length of stay, resource management, reimbursement, emergency department throughput, and more.

#### Patrick Conway leaves CMS for Blue Cross NC

#### By Alicia Gallegos

Patrick Conway, MD, deputy administrator for innovation and quality at the Centers for Medicare & Medicaid Services, is departing his government post to take the reins of Blue Cross and Blue Shield of North Carolina (Blue Cross NC).

In an Aug. 8 statement, Blue Cross NC announced that Dr. Conway will start as the insurer's new president and CEO on Oct. 1. Blue Cross NC's role in transforming the health care system in North Carolina is both a model for other plans and a system that Dr. Conway is excited to further improve, he said in a statement.

"I look forward to collaborating with Blue Cross NC employees, health care providers and employers to deliver the best health outcomes and best service experience at the lowest cost for our customers," he said.

Blue Cross NC Board of Trustees Chair Frank Holding Jr. called Dr. Conway a national and international leader in health system transformation, quality, and innovation who will further advance Blue Cross NC's goals. "His unique experiences as a health care provider and as a leader of the world's largest health care payor will help Blue Cross NC fulfill its mission to improve the health and wellbeing of our customers and communities," Mr. Holding said in the statement.

Dr. Conway joined CMS in 2011 as the agency's chief medical officer and ultimately became the agency's deputy administrator for innovation and quality and director of the Center for Medicare and Medicaid Innovation. Following President Obama's departure from office, Dr. Conway took over as acting CMS administrator for then-CMS principal deputy administrator Andy Slavitt until new administrator Seema Verma assumed the position in March.

A longtime pediatric hospitalist, Dr. Conway was selected as a Master of Hospital Medicine by the Society of Hospital Medicine. He also was elected to the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine in 2014. Prior to joining CMS, Dr. Conway oversaw clinical operations and research at Cincinnati Children's Hospital Medical Center as director of hospital medicine, with a focus on improving patient outcomes across the health system.

### News Flash! Nocturnists are in high demand

#### By Amanda T. Trask, MBA, SFHM

ver 70% of all hospitalist programs have nocturnists, according to the 2016 State of Hospital Medicine Report. For adult-only practices, this has increased to 72.3% from 46.1% in the 2012 State of Hospital Medicine Report.

While one can assert that most hospital medicine practices have nocturnists, not all nights are covered by nocturnists. Thirtynine percent of adult practices report that nocturnists cover 100% of nights, and 9.2% report that less than 25% of nights are covered by nocturnists. So, there remains a great deal of variability in the widespread use of nocturnists for nighttime coverage.

Why is nocturnist presence continuing to increase?

Categorically, nocturnists are hospitalists who work primarily at night, providing in-house coverage for hospitalist admissions and coverage for patients cared for by the hospitalist group.

Other clinicians, such as nurses, patient care technicians, medical technologists, and radiology technologists, have worked night shifts for many, many years. The phenomenon of hospital-based physicians and advanced practice clinicians working only at night is reflective of the needs in an acute care environment.

There are many lifestyle benefits to being a nocturnist – raising a family during the day while working at night, working fewer hours for more pay, and being in high demand.

Nocturnists can also allow a hospitalist group to offer more flexible scheduling options and create career longevity within



Amanda T. Trask, MBA, MHA, FACHE, CMPE, SFHM, is national vice president, Hospital Medicine Service Line, at Catholic Health Initiatives, Englewood, Colo.

the group. Having a nocturnist can allow a group to offer other hospitalists a "day shift only" option and other flexible scheduling options that many seasoned hospitalists are looking for.

#### Demand

Because of the increasing demand, it's becoming more difficult to find longterm nocturnists, and therefore permanent nocturnists are expensive to hire. As reported in the 2016 State of Hospital Medicine Report, groups with nocturnists may offer either a differential in the hours or shifts worked, or compensation, or a combination of both.

About half of nocturnists work fewer



shifts, compared with non-nocturnists. Equally stated, about half of nocturnists work the same number of shifts as their dayonly counterparts. Of those groups whose nocturnists work fewer shifts than their daytime counterparts, about 60% work 1%-20% fewer shifts.

Nearly 70% of groups with nocturnists pay nocturnists differently. The median pay differential is 15%. While this compensation differential is an increase since the 2014 report, it is on par with the 2012 report.

It should not be construed that every practice with hospitalists offers both fewer shifts and more compensation. In fact, there are many who may offer neither and develop other, more creative ways of recognizing the nocturnist differently, such as evaluating scheduled hours per shift (e.g., 8 vs. 10 vs. 12).

#### Responsibility

With more adaptation and remuneration for nocturnists comes more responsibility.

Working as a nocturnist can be grueling. Many times nocturnists may be working alone, and with less support from consultants and fewer hospital resources at night. On the other hand, it's quieter at night and there can be a strong camaraderie from the smaller team at the hospital at night.

Nocturnists, many times, must be comfortable working alone; they must have strong clinical skills, and may need to seek extra training. In fact, in some hospitals the nocturnists may be the primary, or only, physician covering in-house codes.

Nocturnists must also take responsibility to remain abreast of the quality initiatives of the hospitalist group and hospital, since many of the quality committee meetings and hospitalist group meetings typically occur during daytime hours. Nocturnists may need to make an extra effort to feel a part of the group by voluntarily participating in daytime group activities, so that they don't feel like an outsider.

Nocturnists should take the lead in receiving a handoff each evening, and handing off each morning to the day shift. This will likely mean handing off valuable patient care information with more than a few of their hospitalist colleagues. This is so immensely important that national patientsafety-focused organizations have emphasized it for many years.

Since four out of five hospitalist programs have a hospitalist on site at night and the majority of those programs have at least some nocturnist coverage, designing hospitalist programs and staffing models that meet the patient care need of 24/7, in-house coverage is a necessity. Also, given the strong demand for nocturnists, more and more program leaders are being challenged to evaluate creative alternatives to provide sustainable hospitalist services.

Some examples of creative solutions for in-house night coverage are implementing telemedicine for admissions, cross cover, or both; expanding coverage by advanced practice clinicians; and staggering shifts to cover late evenings and early mornings.

Perhaps we'll see more questions about how hospitalist groups are addressing this need in future surveys?

### Student Hospitalist Scholars: The importance of communication

Recognizing that patients often suffer due to breakdowns in communication

#### By Anton Garazha

**Editor's Note:** The Society of Hospital Medicine's (SHM's) Physician in Training Committee launched a scholarship program in 2015 for medical students to help transform health care and revolutionize patient care. The program has been expanded for the 2017-2018 year, offering two options for students to receive funding and engage in scholarly work during their 1st, 2nd, and 3rd years of medical school. As a part of the program, recipients are required to write about their experience on a biweekly basis.

uality improvement in clinical practice has recently become very important to me. What use is clinical knowledge if it cannot be appropriately used to benefit patients in a clinical setting?

Having volunteered at various hospitals since middle school, I became profoundly aware from a young age of the level of clinical knowledge that physicians must possess in order to safely treat their patients. When taking English and psychology classes in college, I became fascinated with the process of communication and common misunderstandings that take place due to different frames of mind.

Throughout my 1st year at medical school, my interest in communication grew. In one class, Essentials of Clinical Reasoning, we were taught to continually consider how to effectively translate our thought processes and potential diagnoses to our patients. To begin crafting effective history of the present illnesses (HPIs), we created complete, whole histories from visit to visit.

At this time, I discovered the subfield of research concerning strategies surrounding handoffs as transition of care changes, with patients often suffering due to breakdowns in communication.

With my interest in handoffs, and with direction from the Society of Hospital Medicine, I reached out to Dr. Vineet Arora, a leading academic hospitalist at the University of Chicago with a highly impressive history of research concerning quality of care toward hospitalized adults. Under the

supervision of Dr. Arora and Dr. Juan Rojas, a pulmonary critical care fellow, I will help investigate whether receiving floor physicians and intensive care unit physicians possess similar shared mental models in regards to the most pertinent point of care – when patients are transferred out of the ICU.

We seek to identify if there are any associations present between readmission from the general floor, the providers' rated likelihood of the patient returning to the ICU, and whether floor and ICU physicians are on the same page concerning condition management while on the floor.



Anton Garazha is a medical student at Chicago Medical School at Rosalind Franklin University in North Chicago. He received his BS in Biology from Loyola University in Chicago in 2015 and his Master of Biomedical Science from Rosalind Franklin University in 2016. Anton is very interested in community outreach and quality improvement and, in his spare time, tutors students in science-based subjects.

I believe the experience I gain at the University of Chicago Medical Center will be invaluable to my future as a physician. I am very excited to get to know the various clinicians at UChicago, to gain clinical experience by observing the management of the general ward, and to identify how effective physicians communicate.

Above all, I hope to use any knowledge I gain this summer to become an efficient, knowledgeable, and compassionate physician capable of providing the highest quality of care to my future patients.

### **Everything We Say and Do: The physician patient**

A physician and cancer survivor walks in her patients' shoes

#### By Neha Sharma, DO

*Editor's note:* "Everything We Say and Do" offers thoughtful communication tactics shared by SHM members for others to adopt in their efforts to improve both the patient and the provider experience.

n May 2007, I received my acceptance letter for medical school. One month later, I was diagnosed with cancer.

The clinic visit was supposed to be only a routine postoperative follow-up after a simple cyst resection. I really hoped that my doctor was mistaken as he walked me through what to expect, and when he was finished, the desperate look in my eyes demanded answers.

When I found out about my acceptance into medical school, I was excited to embark on my journey to be a physician and had ambitious goals for my future. The moment I discovered I had cancer, however, the journey seemed distant and the goals unachievable.

After I fully absorbed the initial shock

of the grave news, I eventually found the strength to analyze the situation at hand. Ultimately, I adopted a more positive outlook and fought cancer head on. Contending with cancer while tackling the rigors of medical school was tedious, but despite the hardships, my experience catalyzed my determination and molded my personality as a physician.

#### What I say and do

I employ active listening and practice patience, especially when it comes to family members.

As both a cancer survivor and a physician, I am able to integrate empathy and diligence by putting myself in my patients' shoes. My experience in a hospital bed during medical school granted me an extremely intriguing perspective towards medicine.

#### Why I do it

When I was a patient, the most crucial thing to my family was information. Most physicians did not take the time to explain my course of care, which elevated my family's angst and anxiety. The experience taught me the importance of patience and communication.

But there were good examples. I still remember the physician who comforted my mother and assuaged her concerns. She held my mother's hand and showed empathy. When my mother cried, she cried. That physician taught me that it was acceptable for physicians to express emotions.

When my surgeon rounded on me in the morning after my procedure, she was not wearing a white coat, which made her appear relatable. Her contagious confidence and humble demeanor were endorsement enough for her capabilities, showing me that a physician's persona supersedes the conventional coat.

#### How I do it

I try to put myself in my patients' shoes. I rejoice with them. I mourn with them. My uninhibited display of emotions affirms empathy. I dissolve all barriers by not wearing a white coat and ask my patients for a partnership. After all, I once walked miles in those shoes.



Dr. Sharma is a chief hospitalist at the Sierra Campus of The Hospitals of Providence, El Paso, Texas. She is a columnist for the El Paso Times and the medical contributor for KVIA Channel 7 ABC News. Her work has appeared on kevinmd.com, Thrive Global, and in El Paso magazine.

### Here's what's trending at SHM

Get the latest news about upcoming events, new programs, and SHM initiatives

#### By Brett Radler

#### Early decision for Fellows applications is Sept. 15. Apply now!

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Hospital Medicine 2018 (HM18) will be held April 8-11,

2018, at the Orlando World Center Marriott. Many cuttingedge abstracts first presented at SHM's Research, Innovations, and Clinical Vignettes sessions go on to be published in respected medical journals. Yours could be next.

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*Mr. Radler is marketing communications manager at the Society of Hospital Medicine.* 

### **Sheak Peek:** Journal of Hospital Medicine

#### By Ryan Greiner, MD; Kristopher Hartwig, MD, MPHIL; and Aimee M. Merino, MD, PHD

A randomized controlled trial of a CPR decision support video for patients admitted to the general medicine service

**BACKGROUND:** Patient preferences regarding cardiopulmonary resuscitation (CPR) are important, especially during hospitalization when a patient's health is changing, yet many patients are not adequately informed or involved in the decision-making process.

**OBJECTIVES:** We examined the effect of an informational video about CPR on hospitalized patients' code status choices.

**DESIGN:** This was a prospective, randomized trial conducted at the Minneapolis Veterans Affairs Health Care System.

**PARTICIPANTS:** We enrolled 119 patients who were hospitalized on the

general medicine service and at least 65 years old. The majority were men (97%) with a mean age of 75.

**INTERVENTION:** A video described code status choices: full code (CPR and intubation if required), do not resuscitate (DNR), and do not resuscitate/do not intubate (DNR/DNI). Participants were randomized to watch the video (n = 59) or usual care (n = 60).

**MEASUREMENTS:** The primary outcome was participants' code status preferences. Secondary outcomes included a questionnaire designed to evaluate participants' trust in their health care team and their knowledge and perceptions about CPR.

**RESULTS:** Participants who viewed the video were less likely to choose full code (37%), compared with participants in the usual-care group (71%), and were more likely to choose DNR/DNI (56% in the video group vs. 17% in the control group) (P < .00001). We did not see a difference in trust in their health care team or knowledge and perceptions about CPR as

assessed by our questionnaire.

**CONCLUSIONS:** Hospitalized patients who watched a video about CPR and code status choices were less likely to choose full code and were more likely to choose DNR/DNI.

Also in JHM this month

#### Influenza season hospitalization trends in Israel: A multi-year comparative analysis 2005/2006 through 2012/2013

**AUTHORS:** Aharona Glatman-Freedman, MD, MPH; Zalman Kaufman, MS; Yaniv Stein, BS; Hanna Sefty, MS; Hila Zadka, PhD; Barak Gordon, MD, MHA; Jill Meron, BSc; Ethel-Sherry Gordon, PhD; Rita Dichtiar, BSc; Ziona Haklai, MSc; Arnon Afek, MD; and Tamy Shohat, MD, MPH

#### Appropriate reconciliation of cardiovascular medications after elective surgery and postdischarge acute hospital and ambulatory visits

**AUTHORS:** Jonathan S. Lee, MD; Ralph Gonzales, MD, MSPH; Eric Vittinghoff, PhD; Kitty K. Corbett, PhD, MPH; Kirsten E. Fleischmann, MD; Neil Sehgal, MD, MPH; and Andrew D. Auerbach, MD, MPH

#### Patterns and appropriateness of thrombophilia testing in an academic medical center

**AUTHORS:** Nicholas Cox, PharmD; Stacy A. Johnson, MD; Sara Vazquez, PharmD; Ryan P. Fleming, PharmD, BCPS; Matthew T. Rondina, MD; David Kaplan, MD; Stephanie Chauv, PharmD; Gabriel V. Fontaine, PharmD; Scott M. Stevens, MD; Scott Woller, MD; and Daniel M. Witt, PharmD, BCPS, FCCP

#### National trends (2007-2013) of Clostridium difficile infection in patients with septic shock: Impact on outcome

**AUTHORS:** Kshitij Chatterjee, MD; Abhinav Goyal, MD; Aditya Chada, MD; Krishna Siva Sai Kakkera, MD; and Howard L Corwin, MD

Blood products provided to patients receiving inappropriate critical care AUTHORS: Thanh H. Neville, MD, MSHS; Alyssa Ziman, MD; and Neil S. Wenger, MD, MPH



### **Sneak Peek:** The Hospital Leader blog

Advanced care documents are the start of a conversation, not the end

By Danielle Scheurer, MD, SFHM, MSCR

#### Wrongful life

There have been recent discussions in the lay media about a growing trend of litigation cases focused not on the "right to live," but rather on the "right to die." These cases have involved patients who received aggressive treatment, despite having documentation of their wishes not to receive such aggressive treatment. Although unsettling, it is not surprising that this issue has arisen, given the national conversations about the exorbitant cost of care at the end of life in the United States and the frequency with which patients do not receive end-of-life care that is concordant with their wishes.

These conversations have spurred providers and patients to discuss and document their wishes, via advanced care directives and/or POLST orders (Physicians Orders for Life-Sustaining Treatment). There is now even a national day devoted to advanced care decision making (National Healthcare Decisions Day).

While these documents are increasingly available for hospitalists and other physicians during a patient's hospital stay, as we all know, they do not always provide complete clarity in decision making for individual scenarios in a patient's care; there is often ambiguity in applying written advanced directives in dynamically changing cases. Ambiguity is also often introduced in circumstances where the patient is no longer able to make decisions, and family members (with or without health care power of attorney) express desires, wishes, and concerns about their loved one's care plan. Some advocate that advanced care planning should be more about teaching patients and families how to make decisions in the moment, rather than documenting a "static" decision.

But for situations when the paperwork is clear and the patient actually does receive undesired aggressive care, more plaintiff attorneys are taking on these cases of the "right to die," since now more people are recognizing and accepting that unwanted life is a type of harm.

This brings to light two important considerations in how we use advanced care planning documentation:

1. These documents should be treated as dynamic decision-making documents, not static documents that are filled out and filed at a single point in time. Patient wishes can and do change due to a variety of factors; any changes should be repeatedly sought to ensure consistency with care plans.

2. These documents should be the start of a conversation, not the end of a conversation. Written documentation can still be fraught with ambiguity; a conversation about the document can help clarify desires and ensure that wishes and care plans match.

In our ongoing desire to "do no harm," overtreatment is increasingly being recognized by patients and families as a type of harm. To avoid these potentially catastrophic situations, we should all use advanced care documentation as the start of a careful conversation about goals of care and treatment choices. Hospitalists should work with their interprofessional team members (for example, case managers, social workers, nurse navigators, and so on) to make sure every patient has, or is at least working on, advance care directives, and guide the patient and family in decision making that puts them at ease. With our patients, we can help ensure concordance between their end-of-life wishes and our care plans.

Read the full post at hospitalleader.org.



#### ALSO ON THE HOSPITAL LEADER BLOG

POST: Follow You, Follow Me By Tracy Cardin, ACNP-BC, SFHM

POST: SHM Movers & Shakers, Hospital Silos & JHM Research in HM News By Felicia Steele

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### When families participate in rounds, errors decrease

By M. Alexander Otto

**NASHVILLE, TENN.** – When families are actively included in pediatric hospital rounds, preventable adverse events drop 38%, and families report better hospital experiences, with no negative impact on rounds duration or teaching, according to a prospective investigation on inpatient pediatric units of seven North American hospitals.

"We [found] that families are excellent reporters of safety, which is an important takeaway for hospitals and hospitalists," said lead researcher Alisa Khan, MD, from the division of general pediatrics at Boston Children's Hospital.

"We always talk about how parents know their children better than anyone else; empowering the family to know what we are looking for can have downstream safety implications," she said. In the study, families often caught problems before medical staff, such as IV infiltrations. They also reported delays in diagnoses and conflicting information, among other things, Dr. Khan explained at the Pediatric Hospital Medicine meeting. There's not much data on family-centered rounds in pediatric medicine, so Dr. Khan and her team decided to investigate. They modified the I-PASS resident handoff model (illness severity, patient summary, action list, situation awareness and contingency planning, and synthesis by receiver) to be more family friendly.

Families were given a short form before rounds that asked if their child was better, worse, or about the same as the day before, and what questions and items they wanted to address. There was also space for them to take notes during the presentation about what had changed overnight, what still needed to be done, and what to look out for.

Families were given the opportunity to speak first during rounds, and medical staff used plain language: "has a fever" instead of "febrile," for instance. At the end of the presentation, families were asked to read back their takeaways.

The investigators compared baseline data from the 3 months before implementation with data for the 3 months afterward. The study included more than 1,500 patients and more than 300 rounds in both the preand postimplementation arms. The chil-



Dr. Alisa Khan

dren were general inpatients; surgery and ICU patients were excluded.

Harmful errors/preventable AEs dropped from 20.7/1,000 patients-days to

12.9/1,000 after implementation, a 38% reduction (P = .01). There was also a reduction in overall AEs from 34 to 18.5/1,000 patient-days (P = .002).

Compared with baseline data, after implementation, families were more likely to report that they understood the medical plan and what was said on rounds. They also were more likely to report that nurses had addressed their concerns and made them feel like an important member of the team.

Direct observation of pre- and postimplementation rounds showed that family and nursing engagement improved and families more often got written updates. There were no statistically significant differences in rounds duration or decreases in teaching.

"Congratulations. This is very impressive work and also the right thing to do," an audience member said after Dr. Khan's presentation at the meeting, sponsored by the Society of Hospital Medicine, the American Academy of Pediatrics, and the Academic Pediatric Association.

The work was funded by the Patient-Centered Outcomes Research Institute and the Agency for Healthcare Research and Quality. Dr. Khan had no disclosures.

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### ospital readmissions enalties now in 5th year

#### CONTINUED FROM PAGE 1

hospital's Medicare reimbursement. Hospitals are being penalized an average of 0.73% of their annual Medicare reimbursement, and cumulative HRRP penalties will reach nearly \$1.9 billion by the end of the fiscal year, Kaiser Health News reports.<sup>2</sup>

Hospital readmissions were discussed by health policy researchers for years, with-

out much impact on policy, but once there were financial implications, there was more action to improve performance, says Harlan Krumholz, MD, director of the Yale New Haven (Conn.) Health System Center



Dr. Krumholz for Outcomes Research and Evaluation and

lead researcher on the center's government contract to develop the 30-day readmission measure used by CMS.<sup>3</sup>

"Basically, we chose to introduce the idea of measuring readmissions because we felt it represented an adverse outcome for kind of concerns people had, the degree to which they understood what had happened to them, the extent to which they were prepared for the next steps."

Once the patient leaves the hospital, there are myriad factors that will influence their likelihood of returning, notes researcher Karen Joynt, MD, MPH, of the department of health policy and management at Harvard's School of Public Health, Boston. "The proportion of patients readmitted to the hospital because of gross error is low, but sometimes we're too optimistic about our patients' ability to manage postdischarge," she said.

"We all know we can do better at providing softer landings, and anyone who's ever been a hospital patient or a family member of one knows that leaving the hospital is incredibly tumultuous. I experienced that with my own parents, and it's frightening, even if everything is done right. It's still a very vulnerable time."

HRRP has fundamentally changed the conversation about hospital care, Dr. Joynt said. "I think we need to change the conversation even more and talk more about how to prevent admissions in the first place. from over 21% to under 18% between 2007 and 2014, although most of the reduction occurred in the first few years after HRRP was announced and has since leveled off.

Other research has tried to explore the relationship between readmissions rates and outcomes that might matter more to patients

or might be better proxies for the quality of the hospital experience. Is readmission rate a true measure of quality or just a utilization measure? Research also has tried to document



what works - what Dr. Jha

are the best strategies for preventing avoidable readmissions by improving the discharge process, care transitions, and the coordination of care postdischarge in the community - although no silver bullet has yet been identified.

A recent effort to inject more equity into the penalties program, contained in the wide-ranging 21st Century Cures Act signed into law by President Obama in December 2016, requires Medicare to account for patients' socioeconomic backgrounds when it calculates reductions in its payments to hospitals under HRRP. The law directs the government to change the way pay for performance is applied to safety net hospitals by setting different penalty thresholds for hospitals based on the proportion of their patients who are dually eligible for Medicare and Medicaid.

It remains to be seen how this will be implemented and with what impact. But some critics have continued to question whether hospitals should be held accountable for readmissions, whether 30 days is the correct time frame for that accountability, and whether some hospitals might be simply taking the penalty hit rather than investing in the hard work of care transitions.

#### Impact on working hospitalists

One expert, Ashish Jha, MD, MPH, director of Harvard's Global Health Institute, wants to see hospitalists get more engaged in the conversation about how to improve hospital care overall.

"It's an open question what is the accountability of individual hospitalists. No doubt thinking about these issues has changed, but I don't think that much has really changed for the frontline hospitalist. Does what's written about readmissions translate to what people are feeling on the

front lines?" he asked. "I'm a hospitalist, and I wish I could set up all of the services that would be needed by my patient at home. I'd send that patient home today if I could. But that kind of redesign requires a lot deeper thinking about what really happens after the patient goes home."

Experts say there aren't metrics available that could allocate penalties to individual hospitalists for their performance in readmissions prevention. But hospitals, clearly, are paying attention, and hospitalist groups may find that part of their negotiation of quality and performance incentives with the hospital includes readmissions.

"At the level of the hospitalist group, there can be more skin in the game, but at the level of the doctor who writes the discharge order, it's more of an individual responsibility to acknowledge their role in making sure that the right steps are taken in the discharge process," said Brian Harte, MD, SFHM, a past president of the Society of Hospital Medicine, who in 2016 was named president of Cleveland Clinic Akron (Ohio) General Hospital.

"There are so many

other variables that go into transitions of care, and it would be unreasonable to try to hold the individual doctor responsible for all of them," he said. But accountability can be passed on to the Dr. Harte hospitalist group. "My



hospital contracts with a national hospitalist company and our agreement has quality measures that we review with them. We ask them to focus on readmissions."

Dr. Harte said that when patients are discharged from the hospital, they go from an environment where everything is taken care of for them, to total responsibility for their self-care. Yet we are asking ever more from patients in terms of self-management.

"We need to focus on the human side of the experience. The hospital is a place to be avoided wherever possible," he said. Yet some readmissions are largely unpreventable. Hospitalists should focus on the patient's greatest risk of preventable readmission. "Is it health literacy? Is it transportation?"

Readmissions at the front lines Preetham Talari, MD, FACP, FHM,

"We all know we can do better at providing softer landings, and anyone who's ever been a hospital patient or a family member of one knows that leaving the hospital is incredibly tumultuous. I experienced that with my own parents, and it's frightening, even if everything is done right. It's still a very vulnerable time."

> -Karen Joynt, MD, MPH, of the department of health policy and management at Harvard's School of Public Health, Boston

many people that was being ignored; that risk could be reduced; and improvements would yield benefits for people as well as save money for the health care system," he told The Hospitalist.

"More than anything, HRRP has sharpened the focus on considering the episode of care from the patient's perspective - rather than just focusing on venues of care like the hospitalization alone," Dr. Krumholz said. "The focus on readmission forced many of us in the health professions to consider what the experience was like to leave the acute setting - how information flowed, what As a clinician, I think we need to be more innovative, recognizing that the ways we'll make a real difference probably has more to do with what happens outside of the hospital. My personal hope is that new alternate payment models like accountable care organizations will lead to more creative partnerships with other providers."

#### What have we learned about readmissions in 5 years?

A lot of recently published research about readmissions has documented modest decreases in overall readmissions nationally,



#### CONTINUED FROM PAGE 14

hospitalist at University of Kentucky HealthCare in Lexington, has an interest in health care safety, quality improvement, and value. He has led the university's site participation in Project BOOST, the Society of Hospital Medicine's national mentored quality improve-

ment initiative for care transitions. Dr. Talari also led a quality initiative at the university called the Interprofessional Teamwork Innovation Model to systematize teamwork, first piloted on Dr. Talari a 30-bed hospitalist



unit where he is medical director. "On the front lines, we've definitely seen

increased emphasis from our senior leadership, which translates into having more tools and time to work on improving transitions and on teamwork," he said. The hospital has provided tools for Dr. Talari and his team to participate in Project BOOST, and made sure that each of its 16 hospital medicine teams includes a dedicated case manager and pharmacist. "We've also partnered with nursing homes and rehabilitation facilities," he noted.

"Readmissions are not just about doctors, they are more about patient factors, socioeconomic factors, where they live," Dr. Talari said. "Those are harder to impact, but in my experience, it comes down to thinking about the patient's needs before discharge - really from the time of admission: What are all the things we can do in the hospital to make sure the patient is safely transitioned home?"

According to Dr. Talari, complex issues like readmissions don't depend on just one, two, or three factors. "But we do the interventions believing that it will improve processes and outcomes, and then add another intervention and another," he said. "All of these interventions will add up like a jigsaw puzzle to achieve a final, sustainable outcome. One thing I believe is hospitalists should be leading these efforts."

#### Better interventions. better infrastructure

Leora Horwitz, MD, MHS, director of the Center for Healthcare Innovation and Deliv-

ery Science at New York University School of Public Health, says the biggest change she has seen resulting from readmissions penalties is that transitions of care are now understood to be both important and the responsibility of front-

line hospitalists. "That was not true 5 or 10 years ago. We used to spend hours admitting patients to the hospital and then 5 minutes on their discharge.'

Dr. Horwitz

Dr. Horwitz also sees a growing body of evidence that change is possible, "not only evidence that intervention works, but that it matters if you get medication reconciliation right, if you connect discharged

everybody by changing your template. Sit down in a room together every afternoon to talk about what will happen to the patients when they go home. That's become standard at our hospital. That was never done before."

"Readmissions are not just about doctors, they are more about patient factors, socioeconomic factors, where they live. Those are harder to impact, but in my experience, it comes down to thinking about the patient's needs before discharge - really from the time of admission: What are all the things we can do in the hospital to make sure the patient is safely transitioned home?"

> -Preetham Talari, MD, FACP, FHM, hospitalist at University of Kentucky HealthCare in Lexington

patients with community services. But you have to throw everything at the problem. The studies that look at only one intervention to improve transitions tend to fail.

"We've also learned that the infrastructure can be built better," she said. Historically, hospital discharge summaries have been abysmal. But we can automate the importation of pending labs into the electronic health record. These are things you can change for

Evidence for improved outcomes is mixed, Dr. Horwitz noted. However, she pointed out, is there any evidence that readmissions penalties have produced adverse outcomes? Did they increase mortality, or length of stay? "So far the evidence suggests that they did not," she said.

"I think it's generally likely that the work we have done has resulted in better care. Thousands of people haven't had to go back to the hospital, and that's a good thing."

#### **Recent research on readmissions penalties**

survey by Yale researchers, published in JAMA in December 2016, found that hospitals financially penalized under HRRP reduced their readmissions rates at a higher rate than nonpenalized hospitals, "which implies that penalties can improve quality and readmission performance for hospitals with the most room for improvement," coauthor Kumar Dharmarajan, MD, MBA, said in a statement.<sup>4</sup> The hospitals responded to external pressures - in other words, financial penalties worked. But most of the reduction happened in the 2 years before actual penalties went into effect, which suggests that further improvement will not be easy, the authors note.

A survey of the attitudes of hospital leaders on HRRP found that it has had a major impact on their efforts to reduce readmissions rates, although the failure to take sociodemographic factors into account was a major complaint for these leaders.<sup>5</sup> Most said the penalties were too large, but 42.5% believed HRRP was likely to improve quality.

Some have questioned whether readmissions penalties were just encouraging hospitals to reduce their rates by keeping returning patients in observation units rather than formally readmitting them. Zuckerman et al. in the New England Journal of Medicine found no evidence that changes in observation unit stays accounted for the documented decrease in readmissions.<sup>6</sup>

But according to Papanicolas et al. in Health Affairs, patient hospital experience has improved only modestly under hospital value-based purchasing for U.S. hospitals,

with no evidence that the program has had a beneficial effect on overall patient experience.7 Another study from Harvard by Figueroa et al. found that evidence is lacking that hospital value-based purchasing leads to lower mortality rates.<sup>8</sup>

More research will be forthcoming from Project ACHIEVE (Achieving Patient-Centered Care Dr. Williams and Optimized Health in Care

Transitions by Evaluating the Value of Evidence), a \$15.5 million initiative funded for 51 months by the Patient-Centered Outcomes Research Institute. Led by Mark Williams, MD, FACP, MHM, chief transformation & learning officer and chief of hospital medicine at the University of Kentucky and principal investigator for SHM's Project BOOST, it aims to identify the most effective strategies in delivering to patients and their caregivers what matters most to them in their hospital and discharge experience.

"Patients and caregivers tell us: Hey, you people are

the experts. You've taken care of lots of people with my medical condition before. You should know what my needs are going to be postdischarge and help me anticipate them," he said.

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### More studies show Medicaid expansion has benefited hospitals

#### But state budget troubles continue to threaten hospital finances

n 2016, a series of studies showed the impact of Medicaid expansion on hospitals.<sup>1</sup> The news was good: Hospitals in states that accepted Medicaid expansion through the Affordable Care Act saw dramatic reductions in their uninsured patient populations, increases in their Medicaid stays, and reductions in uncompensated care costs.<sup>1,2</sup>

In 2017, additional data continue to show that Medicaid expansion has been a boon to hospitals, including an April 2017 report published by the Urban Institute and a May 2017 analysis from The Commonwealth Fund.<sup>3,4</sup> Both show that some of the hospitals that need it most are reaping the greatest benefits of expansion.

We found that small hospitals and hospitals in non-metro areas experienced larger gains in profit margins in states that expanded Medicaid compared to their counterparts in states that did not expand Medicaid," said Fredric Blavin, PhD, senior research associate at the Urban Institute's Health Policy Center. His report was an update to an October 2016 study he authored in JAMA.<sup>5</sup> Notably, he said, these

gains were among hospitals that are "financially vulnerable and prone to closures."

At the same time, Craig Garthwaite, PhD, MPP, lead author of The Commonsaid Medicaid expan-



wealth Fund report, Dr. Blavin

sion "wiped out roughly half of the uncompensated care faced by hospitals, with relatively little or no decline in nonexpansion states." To date, 19 states have not expanded Medicaid.

With Medicaid facing an uncertain

future, Dr. Blavin said some experts are concerned about what could happen to vulnerable hospitals if Medicaid expansion is repealed or scaled back. Indeed, President Trump and congressional Republicans have proposed significantly altering Medicaid either by transitioning it to block grants or by capping federal funding for the entitlement. 6,7

"We wanted to give people a sense of the stakes of what you're talking about with repeal of the Affordable Care Act and [going] back to a system where patients are able to get emergency care at the hospital but not the complete care they get if they're insured. We're not going to be paying hospitals for that care, so the hospital has that coming out of their profit margin," said Dr. Garthwaite, professor of strategy and codirector of the Health Enterprise Management Program in the Kellogg School of Management at Northwestern University, Evanston, Ill.

The Commonwealth Fund report used data from the Centers for Medicare & Medicaid Services (CMS) Hospital Cost Reports to examine 1,154 hospitals in expansion and nonexpansion states. It built on a Health Affairs study Dr. Garthwaite and his coauthors published in 2016.<sup>2</sup> The analysis found that between 2013 and 2014, uncompensated care costs declined dramatically in expansion states and continued into 2015, falling from 3.9% to 2.3% of operating costs. Meanwhile, hospitals in nonexpansion states saw uncompensated care costs drop just 0.3-0.4 percentage points. The largest reductions were seen by hospitals providing the highest proportion of care to lowincome and uninsured patients, and overall savings to hospitals in expansion states amounted to \$6.2 billion.

"Any contraction of the Medicaid expansion will reduce overall health insurance coverage and could have important financial implications for hospitals," Dr. Blavin said. "We are likely to see large increases in expenses attributable to uninsured patients, declines in Medicaid revenue, and increases in uncompensated care burdens that can be a significant financial strain to hospitals."

As part of a project supported by the Robert Wood Johnson Foundation, the Urban Institute in May 2011 began to track and study the impact of health reform. The report Dr. Blavin authored is part of this endeavor and utilized data from the American Hospital Association Annual Survey and the CMS Health Care Cost Reports to update the 2016 JAMA study. It compared hospitals in expansion states to those in nonexpansion states between fiscal years 2011 and 2015, excluding hospitals in states that expanded before January 2014. It examined hospital-reported data on

uncompensated care, uncompensated care as a percentage of total hospital expenses, Medicaid revenue, Medicaid as a percentage of total revenue, operating margins, and excess margins.

The analysis found that Medicaid expansion resulted in a \$3.2 million reduction in uncompensated care and a \$5.0 million increase in mean annual Medicaid revenue per hospital. Expansion-state hospitals also saw improvements in excess and operating margins relative to nonexpansion state hospitals.

However, Ajay Kumar, MD, FACP,

"Any contraction of the Medicaid expansion will reduce overall health insurance coverage and could have important financial implications for hospitals. We are likely to see large increases in expenses attributable to uninsured patients, declines in Medicaid revenue, and increases in uncompensated care burdens that can be a significant financial strain to hospitals."

- Dr. Fredric Blavin

SFHM, chief of medicine at Hartford (Conn.) Hospital, said his hospital has not observed these same

trends. Connecticut expanded Medicaid in 2010. "We have seen some decline in uncompensated care; however, revenue has not improved," Dr. Kumar said. "Medicaid expansion has not been Dr. Kumar economically favorable



to us, not because of the intent of the ACA, but due to state policies."

In Connecticut, Medicaid reimbursement rates are among the lowest in the country.<sup>8</sup> The state uses a provider tax to

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finance Medicaid but, facing a budget deficit, state leaders have dramatically reduced the amount of money returned to hospitals in recent years.<sup>9</sup>

"Our Medicaid patient volume has gone up but our margins have declined because the return on investment is so low," added Dr. Kumar, a practicing hospitalist and member of the SHM Public Policy Committee. He is concerned about what happens if Medicaid is capped or transitioned to a block grant, since "block grants have not been favorable so far ... It would further squeeze us."

In Arizona, Steve Narang, MD, MHCM, a hospitalist and CEO of Banner– University Medical Center Phoenix (B-UMCP), already knows what it's like

when Medicaid fund-



ing expands and then contracts. In 2001, the state expanded Medicaid to 100% of the federal poverty level for childless adults but then in 2011, in the throes of recession, the state froze its match on federal dollars. Prior to the freeze, charity care and bad debt made up 9% of B-UMCP's net revenue. After the state cut Medicaid, the hospital's uncompensated care doubled; charity care and bad

debt spiked to 20% of net revenue. Once the freeze was lifted and the state expanded Medicaid through the ACA in 2014, bad debt and charity care plummeted to 7% of revenue and remains in the single digits, Dr. Narang said.

"You hear a lot, especially in debates, about Medicaid being bad coverage ... From a hospital perspective, if you're taking care of a patient who is uninsured versus a patient with Medicaid coverage, that hospital is likely better off financially treating the patient with Medicaid coverage," said Dr. Blavin.

For Dr. Narang, who practiced as a pediatric hospitalist for more than a decade before becoming a hospital leader, the issue goes beyond the economics of his hospital.

"From a basic commitment to our fellow human beings, are we doing the right thing as a country?" he asked, noting that states and the federal government must address the economic realities of health care while also providing safety nets for patients. "We have to do both. But I have faith that the state and federal government will find a model, and we will continue to focus on what we can control."

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– Dr. Craig Garthwaite

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## How hospitalists can help reduce readmissions

#### CONTINUED FROM PAGE 1

ing patient-centered discharge instructions (that is, making sure they are written in language that patients can understand) or asking transition coaches to help facili-

tate a successful transition," Dr. Herzig said. "This finding is consistent with the fact that the factor most commonly identified as contributing to readmissions was insufficient patient understanding or Dr. Herzig ability to self-manage.



Combined, these findings suggest that strategies to enhance patient understanding of their illness, care plan, and what to expect after hospital discharge, are likely to be important components of successful readmission reduction programs."

Another commonly endorsed strategy to prevent readmission was greater engagement of home and community supports. This entails enlisting the help of social workers and community agencies to deliver meals, provide transportation to doctors' appointments, and so forth. "Inadequate social support contributes to many readmissions," Dr. Herzig said. "Hospitalists should request assistance from social workers in helping to secure assistance for patients who need these services."

Provisioning of resources to patients to help them manage their care after discharge is also recommended. For example, engaging nurses or pharmacists who can help with issues that arise after discharge may help keep patients out of the hospital.

"Hospitalists should be aware of what resources are available to help patients manage their care," Dr. Herzig said. For example, if a patient needs periodic blood pressure monitoring, the hospitalist can tell the patient about free blood pressure checkpoints or suggest a home-automated blood pressure monitor.

The study also showed that improved coordination of care between inpatient and outpatient providers, such as sharing medical records, could reduce readmission rates. "This allows for better inpatient care and increased ability for primary care physicians to react appropriately to issues arising after discharge," Dr. Herzig said. "In the absence of a shared system, hospitalists should complete discharge summaries in a timely fashion and ensure that they're promptly transmitted to primary care physicians."

Finally, the researchers believe that multifaceted, broadly applied interventions may be more successful than those relying upon



This map reflects the number of hospitals in each state that will receive a penalty in fiscal year 2017 under the Hospital Readmissions Reduction Program (HRRP). Performance reporting period for FY 2017 program year was July 1, 2012, to June 30, 2015.

individual providers choosing specific services based on perceived risk factors. "This is because a prior study<sup>5</sup> demonstrated that it is difficult to anticipate in advance which patients will be readmitted, and, in our study, physicians did not agree on the factors that contributed to a given readmission," Dr. Herzig explained. "Because of these findings, it becomes hard to rely on physicians to identify patients at increased risk for readmission, and to direct services that correctly anticipate contributing factors. Instead, it seems that programs aimed at improving general processes for particular patient categories may be more successful at reducing readmissions." For example, it might be better to use a transition coach for all patients over the age of 65, rather than relying on physicians to decide which patients are at high risk for readmission.

Dr. Herzig said it's important to note that hospitalists and primary care physicians had different appraisals of reasons for readmission. Therefore, when designing readmission reduction programs or determining specific services to prevent a readmission for a given patient, it is important for hospitalists to obtain input from primary care physicians to ensure that they address all of the potential contributors to readmission for a given patient.

#### Interviewing patients regarding readmissions

After involved clinicians and independent physician reviewers performed extensive case reviews of more than 700 readmitted patients,<sup>6</sup> Ashley Busuttil, MD, FHM, associate section chief, hospital medicine, University of California, Los Angeles, department of medicine, and executive medical director, medicine services, UCLA department of medicine; and Erin Dowling, MD, assistant clinical profes-

sor, general internal medicine, hospitalist services, UCLA Medical Center, Santa Monica, Calif., and their colleagues were unable to identify which readmissions could have easily been prevented, and found



Dr. Busuttil

causality varied extensively.

Given this, the researchers set out to identify a more nuanced understanding of why patients return to the hospital. They decided to do this by talking to patients directly and specifically studied patient readiness from the patient perspective.

Through interviews with patients, the researchers determined that patients were more likely to think that their readmissions were preventable if they felt unready for discharge during their initial hospitalization. This was despite the fact that patients met what clinicians would consider "ready" by objective, providercentric criteria: They were medically stable, they had in-home support services, they had follow-up arranged, and so forth. As such, the researchers wanted to put effort into educating and preparing patients for what the patients' homes will look and feel like posthospitalization to address their feelings of unreadiness.

To that end, the researchers created an enhanced transition initiative that included showing an educational video near the time of admission and a patient-centered discharge checklist to help patients identify questions they might have after discharge. The discharge checklist asks patients to put themselves in the position of being at home and to imagine working through scenarios they might face so they will know how to deal with such situations if they arise. For example, if you have pain, who should you call? What should you do if you run out of medication?

Dr. Dowling believes that the hospitalist will, over time, become essential to assessing

patient readiness. "As we learn more about how patients approach discharge, hospitalists' understanding of patient needs beyond straightforward medical care will be crucial to having smoother transitions of care." she said.



The researchers also

explored pain control. As a health system, UCLA Medical Center has formed a multidisciplinary task force to optimize its approach to pain control. "If we can address comfort - for both patients at high risk of readmission and those that aren't – we hope we can improve symptom control overall," Dr. Busuttil said. "It's not uncommon for CONTINUED ON PAGE 22

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"As we learn more about how patients approach discharge, hospitalists' understanding of patient needs beyond straightforward medical care will be crucial to having smoother transitions of care."

> -Erin Dowling, MD, assistant clinical professor, general internal medicine, hospitalist services, UCLA Medical Center, Santa Monica, Calif.

#### CONTINUED FROM PAGE 20

patients to feel inadequate symptom control at discharge. While this is likely only one component of all the readmission pieces, a patient who feels that their symptoms are not controlled is likely to feel less ready for discharge. Increasing patient readiness, perhaps by increasing symptom control and improving communication regarding symptom management expectations, is a task that the hospitalist is well positioned to address."

In addition, a focus group that included patient representatives was conducted to identify potential discharge paperwork enhancements. Patients were asked to identify opportunities for improvement in the health system's discharge After Visit Summary (AVS). "We were surprised to learn that even though patients knew that they had follow-up appointments, they were unable to locate the follow-up appointment section on the AVS," Dr. Busuttil said. "We also learned that the medication section was confusing. Efforts for an AVS revision are underway."

The researchers also wanted to find out why patients may not use available outpatient resources, and assessed them for decisional conflict – a measure of certainty with decision making - when selecting from multiple options for accessing medical care if they were home postdischarge and began to feel ill again. "Patients with decisional conflict were more likely to state that they would go the emergency room rather than call their primary medical physician or visit an urgent care center," Dr. Busuttil said.

The health system continues to screen patients for decisional conflict. "When positive, we provide bedside education on when to seek medical care through primary care, urgent care, or the emergency department," Dr. Busuttil said. "We also provide patients with information on how to access each of these resources."

While a prior discharge plan may have seemed ideal on paper, time and time again it's not logistically possible for certain patients. "By having this knowledge gleaned from patient interviews, hospitalists are able to provide feedback to health systems regarding different options of outpatient care that may work for the different patient populations they serve," Dr. Dowling said.

To understand why one particular patient population is being readmitted requires taking the time to understand that population, Dr. Dowling noted. "While many validated risk stratification tools are available, they may only serve as general guides," she said. "To impact the population you serve, you must first understand the readmission process as it looks to them."

#### Employing the HOSPITAL score

In another effort to reduce hospital readmissions, Jacques Donzé, MD, MSc, associate physician, Bern University Hospital, Switzerland, and research associate, Brigham and Women's Hospital, Boston, and his colleagues used the HOSPITAL score to identify patients at high risk of 30-day potentially avoidable readmission.

To reduce hospital readmissions most efficiently, hospitals need to target complex and intensive discharge interventions for patients at high risk of potentially avoidable readmission who are more likely to benefit.2 "However, prior research indicates that clinical health care providers are not able to accurately identify which patients are at high risk for readmission," Dr. Donzé said.

In their large international multicenter external validation study, Dr. Donzé and his colleagues found that the HOSPITAL score accurately predicted the risk of 30-day potentially avoidable readmissions. The HOSPITAL score is easy to use and can be calculated before discharge, which makes it a practical tool for identifying patients at high risk for prevent-

able readmission and the timely administration of high-intensity interventions designed to improve transitions of care.<sup>2</sup>

Dr. Donzé believes that several factors may influence the perfor- Dr. Donzé mance of a predic-

tion model, such as the initial selection of the potential predictors, the quality of the derivation method, including readily available predictors commonly available, and including reliable factors that aren't subject to subjective evaluation. "All of these factors can play a role in the performance and generalizability of the HOSPITAL score," he said.

When a patient is identified as high risk to be readmitted, hospitalists can take certain actions to prevent readmission. "Interventions are more likely to be effective when they include several components," Dr. Donzé said. "These include follow-up phone calls and/or home visits, review of the patient's medication list, patient education, and sending a discharge summary to the patient's primary care physician in a timely manner. For now, enough evidence for a specific effective multimodal intervention to be generalizable to the majority of patients is lacking."

Currently, the HOSPITAL score has been validated in approximately 180,000 patients in 14 hospitals across five countries and three continents – always showing good performance and generalizability. The HOSPITAL score includes seven variables

D

readily available before hospital discharge, is easy to use, and is the most widely validated prediction model for readmission, Dr. Donzé said.

Before being implemented into practice, a score should ideally reach the highest level of validation, that is, show its clinical impact. "We expect that the score will not only be able to accurately predict high-risk patients, but using the score will also impact patient care by reducing readmissions when coupled with an appropriate intervention," Dr. Donzé said.

In summary, research has shown that a variety of methods can be used to reduce hospital readmissions, including studying inpatient and outpatient physicians' perspectives regarding factors contributing to readmission, interviewing patients regarding readmissions, and identifying patients at high risk of readmission using the HOSPITAL score.

Many researchers are continuing their studies in these areas.

Karen Appold is a medical writer in Pennsylvania.

#### **Using hospitalist** reflections as a means to reduce readmissions

Deadmission studies and the development of readmission Scoring systems and prediction tools rely on data from a large number of patients, typically extracted from administrative databases.

To complement this data, Deanne

Kashiwagi, MD, consultant, hospital internal medicine, Mayo Clinic, Rochester, Minn., and her colleagues asked hospitalists to reflect upon the readmissions of patients for whom Dr. Kashiwagi they cared to add



insight into the culture of patient care transitions within the health system.

"We felt there was some value in considering these nuances of the local care environment, which may not be represented in studies drawing from large databases, as potential targets for readmission efforts," she said.

Dr. Kashiwagi and her colleagues developed a chart review tool to guide hospitalists through reflection about their patients' admissions and readmissions. "We included factors frequently cited in the literature as contributors to readmissions and CONTINUED ON FOLLOWING PAGE







### 'Observationists': Ready for prime time in an internal medicine residency program



Dr. Nand is medical director, care management & observation unit, and associate program director, internal medicine residency program, at the University of Illinois College of Medicine/ Advocate Christ Medical Center, in Chicago. he Institute of Medicine, in its report "Hospital-Based Emergency Care – At the Breaking Point," has identified Observation Units (OUs) as a "particularly promising" technique to improve patient

flow.<sup>1</sup> Many hospitals across the country either already have them or are in the process of establishing such units. Multiple studies have shown that a highly efficient OU can save billions in health care costs.<sup>2</sup> Historically, such units have existed

within and are staffed by emergency departments. Since the implementation of the two-midnight rule in October 2013, the complexities of observation care changed dramatically from run-of-the-mill 30- to 40-year-old chest pain patients to 80- to 90-year-olds with multiple comorbidities being placed in observation.<sup>3</sup> In many cases, this shifted the care out of the emergency department and into the arena of hospital medicine.

OUs are traditionally managed either by emergency medicine or hospitalists. SHM, in a white paper, concluded: "Collaboration between hospitalists, emergency physicians, hospital administrators, and academicians will serve not only to promote outstanding observation care, but also to focus quality improvement and research efforts for the observation unit of the 21st century."<sup>4</sup>

At our institution OUs are staffed by internal medicine residents supervised by faculty 24/7 year round. This, we believe, is a unique model. We implemented our model after a mini SWOT (strengths, weaknesses, opportunities, and threats) analysis in August 2014. The biggest strength was that we were educating the next generation of "Observationists" as we improved the quality of care delivered to our patients. Our biggest opportunity was no existing curriculum for teaching internal medicine residents the art of observation medicine. So we designed our own. Just like Peter Drucker said, "The best way to predict the future is to create it."

The curriculum is extremely innovative and exposes our residents to both the business and administrative aspects of OUs. Upon surveying our own residents anonymously within 6 months of instituting this rotation, over 90% felt this to be a valuable rotation toward their training. Since we went live, some of our residents who have graduated are now leading OUs at other hospitals.

To measure our program outcomes, we developed a dashboard with multiple metrics for our team. With such data, this rotation became an incubator for our residents for quality improvement projects. They have developed, implemented, and published multiple abstracts, presented posters and even won the first place for innovation at the Midwest Regional Society of General Internal Medicine conference.<sup>5-8</sup>

We have learned many lessons, and every challenge has been addressed as an opportunity. The first lesson was that we needed strong physician leadership to act as the gatekeeper to the unit. Second, as the rotation matured, we always kept our focus on high-quality patient care; we created a quality dashboard which includes length of stay, falls, and patient satisfaction as examples. Last but not least, we stayed mindful of stakeholder buy in, which for us was primarily our residents. We created the curriculum that provides the next generation of internists the broad experience of medicine, with the appropriate amount of autonomy and supervision. This, we believe, is a winwin proposition for all stakeholders – hospitals, physicians, residents, and most importantly the patients we serve. Additionally, data at our institution show that our resident-run units are educationally, clinically, and financially beneficial to the residency programs and the hospitals.

Teaching and exposure to observation medicine is not currently a mainstay in many internal medicine residency programs. Our program provides a framework to establish an observation medicine rotation, which exposes residents to quality metrics and expands their scope of medical education.

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#### CONTINUED FROM PREVIOUS PAGE

added factors that our study group, after a chart review of 40 patients' readmissions, identified as variables contributing to our own patients' readmissions," Dr. Kashiwagi said. "Some of these variables reflected our local care system, such as our staffing model, which led to some patients being cared for by more than two hospitalists during their admission. The study group considered such variables as potential contributors to our own group's readmissions, but they were not necessarily common readmission risk factors identified in large-scale studies."

Dr. Kashiwagi believes that including elements of local practice and culture was the strength of their work. "Groups interested in replicating this reflective process should consider including factors specific to their practices that may contribute to readmission," she said.

Asking hospitalists to perform reviews has led to implementing changes. Physicians were prompted to schedule earlier follow-up appointments and nurse practitioners and physician assistants have worked to improve the quality of their discharge summaries. The exercise also engaged hospitalists in suggesting system changes that might contribute to decreased readmissions, such as a geriatrician-run service (which was recently begun) to provide multidisciplinary acute geriatric care for older hospitalized adults.

"Although large-scale studies are clearly important, readmission review at a more granular level may have merit as well," Dr. Kashiwagi said, noting that such reviews identify local practice factors that groups may quickly act upon to help decrease readmissions. "Hospitalists readily engaged in this reflective exercise, which yielded actionable information to decrease readmissions."

In commenting on why a similar study<sup>7</sup> didn't mimic the results of Mayo Clinic's study, Dr. Kashiwagi said there were some differences in methodology that may explain the difference in readmission rates. "First, this group excluded patients on dialysis, which in our study was a common comorbidity of our readmitted patients," she said. "It is also notable that the chart review tool was different. Perhaps there is less representation of local factors unique to that hospitalist group and their practice culture than on our review form. These investigators also discussed their readmissions at routine intervals. Additionally, their preintervention readmission rate was lower than Mayo Clinic's group, and although the readmission rate trended downward postintervention, it did not reach statistical significance." III

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# Measuring hospital-acquired infection in a new way

#### A new infection composite score can improve patient safety

very day, hospitalists struggle with health care–associated infections, which 1 in 25 patients experiences, according to the Centers for Disease Control and Prevention.

These infections are often discussed in terms of the standardized infection ratio (SIR), but that measure may not assess overall performance, according to a study suggesting a new measure that could help large hospital systems better evaluate their infection outcomes by comparing them with those of their peers.

The researchers piloted an infection composite score (ICS) in 82 hospitals under a single health system. The ICS is a combined score for central line–associated bloodstream infections, catheterassociated urinary tract infections, colon and abdominal hysterectomy surgical site infections, and hospital-onset methicillinresistant *Staphylococcus aureus* bacteremia and *Clostridium difficile* infections. The researchers calculated individual facility ICS scores and compared them with system scores for baseline and performance.

This gives hospitals a more current picture of how they're doing, compared with the SIR, said Mohamad J. Fakih, MD, MPH, of Ascension Health, Grosse Pointe Woods, Mich., lead author of the study. "The SIR is a ratio based on a baseline that's usually a few years prior; it's not the year directly before. So, when we published this paper, some of the infections had a baseline of 2006 through 2008 for the central line infections."

Another difference is that the ICS gives the six infections the same weight, rather than combining them. "So, if you add them up together and then you divide by six, you get a score that tells you how you're doing for infection, compared [with] the whole system. If they have a problem that's related to many infec-

valsartan/kg/day. The adverse embryo-fetal effects of ENTRESTO are attributed to the angiotensin receptor antagonist activity.

Pre- and postnatal development studies in rats at sacubitril doses up to 750 mg/kg/day (4.5-fold the MRHD on the basis of LBQ657 AUC) and valsartan at doses up to 600 mg/kg/day (0.86-fold the MRHD on the basis of AUC) indicate that treatment with ENTRESTO during organogenesis, gestation and lactation may affect pup development and survival.

#### 8.2 Lactation

#### Risk Summary

There is no information regarding the presence of sacubitril/valsartan in human milk, the effects on the breastfed infant, or the effects on milk production. Sacubitril/valsartan is present in rat milk. Because of the potential for serious adverse reactions in breastfed infants from exposure to sacubitril/valsartan, advise a nursing woman that breastfeeding is not recommended during treatment with ENTRESTO.

#### Data

Following an oral dose (15 mg sacubitril/15 mg valsartan/kg) of [<sup>14</sup>C] ENTRESTO to lactating rats, transfer of LBQ657 into milk was observed. After a single oral administration of 3 mg/kg [<sup>14</sup>C] valsartan to lactating rats, transfer of valsartan into milk was observed.

#### 8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

#### 8.5 Geriatric Use

No relevant pharmacokinetic differences have been observed in elderly ( $\geq$ 65 years) or very elderly ( $\geq$ 75 years) patients compared to the overall population [see Clinical Pharmacology (12.3) in the full prescribing information].

#### 8.6 Hepatic Impairment

No dose adjustment is required when administering ENTRESTO to patients with mild hepatic impairment (Child-Pugh A classification). The recommended starting dose in patients with moderate hepatic impairment (Child-Pugh B classification) is 24/26 mg twice daily. The use of ENTRESTO in patients with severe hepatic impairment (Child-Pugh C classification) is not recommended, as no studies have been conducted in these patients *[see Dosage and Administration (2.4), Clinical Pharmacology (12.3) in the full prescribing information].* 

tions, then you know the culture of infection prevention in that hospital is much worse. It's not just one product. There's something much more worrisome for that hospital."

This simple score can be adjusted according to a particular hospital's needs. "Let's say you want to focus on additional infections that are publicly reported. You can add them to that score," Dr. Fakih says. "And you can change the weight in a way depending on what you want to focus on, or, if you want to focus on something more than others, you can increase the weight."

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#### Quick byte Is deprescribing becoming a trend?

bout a third of adverse events during hospitalizations involve a drug-related harm, resulting in longer hospital stays and increased costs, according to the New York Times. "The Institute of Medicine estimated that there are 400,000 preventable adverse drug events in hospitals each year, costing \$3.5 billion. One-fifth of patients discharged from the hospital have a drug-related complication after returning home, many of which are preventable." **IFI** 

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#### 8.7 Renal Impairment

No dose adjustment is required in patients with mild (eGFR 60 to 90 mL/min/1.73 m<sup>2</sup>) to moderate (eGFR 30 to 60 mL/min/1.73 m<sup>2</sup>) renal impairment. The recommended starting dose in patients with severe renal impairment (eGFR <30 mL/min/1.73 m<sup>2</sup>) is 24/26 mg twice daily [see Dosage and Administration (2.3), Warnings and Precautions (5.4) and Clinical Pharmacology (12.3) in the full prescribing information].

#### **10 OVERDOSAGE**

Limited data are available with regard to overdosage in human subjects with ENTRESTO. In healthy volunteers, a single dose of ENTRESTO 583 mg sacubitril/617 mg valsartan, and multiple doses of 437 mg sacubitril/463 mg valsartan (14 days) have been studied and were well tolerated.

Hypotension is the most likely result of overdosage due to the blood pressure lowering effects of ENTRESTO. Symptomatic treatment should be provided.

ENTRESTO is unlikely to be removed by hemodialysis because of high protein binding.

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### Hospitalists lead in palliative care Study shows more palliative care consultations



ccording to a recent report, hospitalists made nearly half (48%) of all palliative care referrals in hospitals in 2015. The report comes from the Center to Advance Palliative Care and the National Palliative Care Research Center.

"The most important finding from this analysis is the near doubling of the number of people receiving palliative care services in U.S. hospital palliative care programs, from an average of 2.7% in 2009 to an average of 4.8% in 2015," said Diane Meier, MD, director of the Center to Advance Palliative Care. "This suggests increasing recognition of the benefits of palliative care by health professionals and greater likelihood that those living with serious illness will receive state-of-the-art care."

The report shows that hospitalists are the No. 1 source of referral to palliative care teams. "They see up close the suffering of their patients and families, their need for comprehensive whole-person care, and the beneficial impact of the added layer of support that palliative care provides," she said.

"Hospitalists should work alongside their palliative care colleagues to develop standardized screening tools so that all patients and families who could benefit have access to the best quality of care during serious and complex illness," Dr. Meier said. Hospitalists can also gain skills in communicating about prognosis and conducting family meetings, as well as safe and effective symptom management, through the online clinical training curriculum available at capc.org.

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1. National Palliative Care Registry. How We Work: Trends and Insights in Hospital Palliative Care. https://registry.capc.org/wp-content/uploads/2017/02/How-We-Work-Trends-and-Insights-in-Hospital-Palliative-Care-2009-2015.pdf. Accessed April 7, 2017.

## Improving outcomes for children with chronic conditions

#### A new approach to treatment shows benefits

incinnati Children's Hospital Medical Center improved outcomes for 50% of pediatric patients by redesigning the way it cares for children with active chronic conditions, according to a new study.

The hospital implemented a Condition Outcomes Improvement Initiative, in which specialized clinical teams applied quality improvement principles to improve outcomes for pediatric patients with chronic illnesses.

Each improvement team focused on a specific chronic condition, such as juvenile arthritis, asthma, chronic kidney disease, or sickle cell disease. The improvement processes implemented included reviewing evidence to choose which outcomes to measure, developing condition-specific patient registries and data collection tools, classifying patients into defined risk groups, planning care before and after visits, and providing self-management and caregiver/parent support for patients and their families.

Study lead author Jennifer Lail, MD, FAAP, analyzed data from more than 27,000 pediatric patients from 18 improvement teams. Following implementation of the changes, half of patients had an improved outcome, and 11 of the 18 chronic condition teams achieved the goal of 20% improvement in their chosen

#### FDA approves two new antibiotic tests



Two new ways to help hospitalists use antibiotics more effectively

ospitalists have two new FDA-approved tools available to help them make antibiotic treatment decisions. The first is the expanded use of the Vidas Brahms PCT Assay, intended to be used in the hospital or emergency room. The test uses - for the first time - procalcitonin (PCT), a protein associated with the body's response to a bacterial infection, as a biomarker that can help hospitalists make antibiotic management decisions in patients with those conditions. The results can help them determine if antibiotic treatment should be started or stopped in patients with lower respiratory tract infections (such as community-acquired pneumonia) and stopped in patients with sepsis.

The FDA has also allowed marketing of the PhenoTest BC Kit. This one is another first, the first test to identify organisms causing bloodstream infections and provide information about the antibiotics to which the organism is likely to respond.

The test can identify bacteria or yeast from a positive blood culture in approximately 1.5 hours (compared with traditional identification and antibiotic susceptibility tests, which can take one to two days). The test can identify 14 different species of bacteria and two species of yeast that cause bloodstream infections. It also provides antibiotic sensitivity information on 18 antibiotics. In addition, the test will identify the presence of two indicators of antibiotic resistance.

For more information on joining SHM and on the "Year of the Hospitalist," visit **www.hospitalmedicine.org**.

clinical outcome, suggesting that clinical teams implementing quality improvement methods with multidisciplinary support can improve outcomes for populations with chronic conditions.

#### Reference

1. Lail J, et al. Applying the Chronic Care Model to Improve Care and Outcomes at a Pediatric Medical Center. Joint Commission Journal on Quality and Patient Safety. 2017;43(3):101-112.



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#### CLINICAL



# How to manage bleeding in patients taking direct oral anticoagulants (DOACs)

DOACs carry a low but significant risk of bleeding, including life-threatening bleeding

By Tyler Albert, MD; David Garcia, MD; Scott Hagan, MD; and Ronald Huang, MD, MP

#### **KEY POINTS**

- The risk of major bleeding, and the case fatality rate of major bleeding, is significantly lower in patients taking DOACs versus VKAs
- For the majority of patients with bleeding on DOACs, supportive care and withholding anticoagulation is sufficient
- Idarucizumab is a novel and effective antidote to dabigatran, but should be reserved for patients with life-threatening bleeding
- Patients with DOACassociated bleeding should be restarted on anticoagulation as soon as it is safe to do so

### The case

A 72-YEAR-OLD MAN with a history of nonvalvular atrial fibrillation (AF) and hypertension presents to the ER after an episode of hematochezia. He is prescribed dabigatran 150 mg twice daily for his AF and took his evening dose 2 hours prior to presentation. His initial exam reveals vital signs of BP 120/55, HR 105, RR 14, and bright red stool on rectal exam. His hemo-globin is 8.1 g/dL, down from 12.0 g/dL one month ago. He has normal renal function. How should you manage his gastro-intestinal bleeding?



#### Background

Direct oral anticoagulants (DOACs) consist of two classes of drugs: oral factor Xa inhibitors (apixaban, edoxaban, and rivaroxaban) and direct thrombin inhibitors (dabigatran). They have gained substantial popularity since their commercial introduction in 2010, and are now Food and Drug Administration approved for the treatment of atrial fibrillation (AF) and venous thromboembolism (VTE) in noncancer patients. DOAC use will likely increase given favorable safety profiles, reliable pharmacokinetics, and recent guidelines recommending their use over vitamin K antagonists (VKAs) for treatment of VTE in noncancer patients.<sup>1</sup>

A primary concern about the routine use of DOACs has been the lack of commercially available direct reversal agents. Unlike warfarin, which has an effective rapid antidote, no direct reversal agent is available for Xa inhibitors, and only recently has there been FDA approval for idarucizumab, a direct thrombin inhibitor reversal drug. Therefore, clinicians are often left wondering how to manage bleeding episodes in patients receiving DOACs.

#### Literature review

*What is the risk of bleeding for patients taking DOACs?* 

DOACs carry a low but significant risk of bleeding, including life-threatening bleed-

ing. There are now robust data from more than 100,000 patients in randomized clinical trials of nonvalvular AF and VTE comparing the risk of major and fatal bleeding between DOACs and VKAs.<sup>2</sup> These trials reveal an annual major bleeding rate of 2%-4% in patients with AF and 1%-2% in patients with VTE taking DOACs.

Importantly, DOACs were found to carry a statistically lower risk of major and fatal bleeding than VKAs. Patients taking DOACs have a relative risk of major bleeding of 0.72, compared with VKAs, and a RR of fatal bleeding of 0.53. Additionally, the case fatality rate for major bleeding episodes was 7.6% for DOACs versus 11.0% for warfarin, despite not having an available antidote for DOACs in these trials.<sup>3</sup> Although there is an increased risk of bleeding from DOACs, the rates of major bleeding and of serious complications from bleeding are lower than with warfarin.

#### How long does the effect of a DOAC last?

A significant advantage of DOACs over VKAs in the setting of bleeding is their shorter half-lives, which range from a low estimate of 5 hours for rivaroxaban to a high estimate of 17 hours for dabigatran<sup>4-8</sup> (Table 1). Given that it takes 4-5 half-lives for a drug to be functionally eliminated, coagulation typically normalizes in patients taking DOACs within 1-3 days, compared with 3-5 days for warfarin. All DOACs have significant renal clearance, and renal failure will prolong the duration of anticoagulation. For patients who are taking DOACs and present with bleeding, it is important to assess their renal function.

#### Are coagulation tests helpful when assessing the effect of DOACs?

Prothrombin time (PT/INR) and activated partial thromboplastin time (aPTT) should be measured in all patients presenting with significant bleeding, whether or not the patient is taking a DOAC. PT and aPTT are commonly elevated for patients taking direct thrombin inhibitors and Xa inhibitors. Although a prolonged PT and/ or aPTT can be useful in determining if the anticoagulant effect from DOACs is still present, normal values of these tests do not rule out an anticoagulant effect in patients taking DOACs.<sup>9,10</sup> Thrombin Time (TT) is a widely available test with quick results, and a normal value rules out the therapeutic effect of dabigatran. Finally, the anti-factor Xa assay is a sensitive test for Xa inhibitors, but requires calibration to the DOAC of interest in order to be reliable. Clinicians should consult with their institution's laboratory prior to using an anti-factor Xa level to test the anticoagulant effect of a specific DOAC. Repeat coagulation testing may be useful in some clinical circumstances, especially if a patient has renal impairment.

#### Are there reversal agents for DOACs?

In October 2015, the FDA approved idarucizumab, a monoclonal antibody fragment that binds dabigatran with much greater affinity than thrombin, thus quickly reversing the effect of the direct thrombin inhibitor. FDA approval came in response to an interim analysis of an ongoing open-label trial, RE-VERSE AD.<sup>11</sup> This study enrolled 90 adults with major bleeding or need for an emergency procedure taking dabigatran to receive idarucizumab (2.5 g in 50 mL rapid infusion dose given twice less than 15 minutes apart for a total of 5 g). Idarucizumab immediately reversed the effect of dabigatran on clotting tests in 88%-98% of the patients. For patients with major bleeding, the median time for bleeding cessation was 11.4 hours. One thrombotic event was reported within 72 hours of drug administration. Therefore, in patients taking dabigatran with an elevated TT, idarucizumab may be used if the bleeding is life threatening and

#### KEY CLINICAL QUESTION | continued from page 30

Table 1: Pharmacologic Profiles of Xa and Direct Thrombin Inhibitors4-8, 23				
Dialyzable?				
No				
Yes				
No				
No				

tmax = time to peak serum concentration after ingestion, t1/2= serum half-life, CrCl= creatinine clearance in mL/min

\*Average values assuming normal hepatic function. Aside from dabigatran, which has minimal hepatic clearance, all other DOACs can have prolonged half-lives in hepatic impairment.

refractory to initial supportive measures.

There are no FDA-approved antidotes for the factor Xa inhibitors. One promising

agent is and exanet-alfa, an inactivated form of factor Xa that irreversibly binds Xa inhibitors. The ongoing, open-label ANNEXA-4 trial<sup>12</sup> reported a decrease in anti–factor Xa activity of ~90% after bolus administration of the drug followed by 2-hour infusion in

67 patients with life-threatening bleeding, with clinical hemostasis achieved in 79% in patients by 12 hours. However, thrombotic

#### SAMSCA® (tolvaptan) tablets for oral use

BRIEF SUMMARY OF PRESCRIBING INFORMATION (For complete details, please *see Full Prescribing Information and Medication Guide.*)

WARNING: INITIATE AND RE-INITIATE IN A HOSPITAL AND MONITOR Serum Sodium

SAMSCA should be initiated and re-initiated in patients only in a hospital where serum sodium can be monitored closely. Too rapid correction of hyponatremia (e.g., >12 mEq/L/24 hours) can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death. In susceptible patients, including those with severe malnutrition, alcoholism or advanced liver disease, slower rates of correction may be advisable.

**INDICATIONS AND USAGE:** SAMSCA is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH).

**Important Limitations:** Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with SAMSCA. It has not been established that raising serum sodium with SAMSCA provides a symptomatic benefit to patients.

**CONTRAINDICATIONS:** SAMSCA is contraindicated in the following conditions: **Urgent Need to Raise Serum Sodium Acutely:** SAMSCA has not been studied in a setting of urgent need to raise serum sodium acutely.

Inability of the Patient to Sense or Appropriately Respond to Thirst: Patients who are unable to auto-regulate fluid balance are at substantially increased risk of

incurring an overly rapid correction of serum sodium, hypernatremia and hypovolemia. Hypovolemic Hyponatremia: Risks associated with worsening hypovolemia, including

complications such as hypotension and renal failure, outweigh possible benefits. **Concomitant Use of Strong CYP 3A Inhibitors:** Ketoconazole 200 mg administered with tolvaptan increased tolvaptan exposure by 5-fold. Larger doses would be expected to produce larger increases in tolvaptan exposure. There is not adequate experience to define the dose adjustment that would be needed to allow safe use of tolvaptan with strong CYP 3A inhibitors such as clarithromycin, ketoconazole, itraconazole, ritonavir, indinavir, neffinavir, saquinavir, nefazodone, and telithromycin. **Anuric Patients:** In patients unable to make urine, no clinical benefit can be expected. **Hypersensitivity:** SAMSCA is contraindicated in patients with hypersensitivity (e.g. anaphylactic shock, rash generalized) to tolvaptan or any component of the product. **WARNINGS AND PRECAUTIONS:** 

Too Rapid Correction of Serum Sodium Can Cause Serious Neurologic Sequelae (see BOXED WARNING): Osmotic demyelination syndrome is a risk associated with too rapid correction of hyponatremia (e.g., >12 mEq/L/24 hours). Osmotic demyelination results in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma or death. In susceptible patients, including those with severe malnutrition, alcoholism or advanced liver disease, slower rates of correction may be advisable. In controlled clinical trials in which tolvaptan-treated subjects with a serum sodium <130 mEq/L had an increase in serum sodium grater than 8 mEq/L at approximately 8 hours and 2% had an increase greater than 12 mEq/L at 24 hours. Approximately 1% of placebo-treated subjects with a serum sodium <130 mEq/L had a rise greater than 8 mEq/L at 8 hours and no patient had a rise greater than 12 mEq/L/24 hours. Osmotic demyelination syndrome has been reported in association with SAMSCA therapy. Patients treated with SAMSCA should be monitored to assess serum sodium concentrations and neurologic status, especially during initiation and after titration. Subjects with SIADH or very low baseline serum sodium concentrations may be at greater risk for too-rapid correction of serum sodium. In patients receiving SAMSCA who develop too rapid a rise in serum sodium. In patients receiving SAMSCA who develop too rapid a rise in serum sodium, discontinue or interrupt treatment with SAMSCA and consider administration of hypotonic fluid. Fluid restriction during the first 24 hours of therapy with SAMSCA and consider administration of serum sodium, and should generally be avoided. Co-administration of serum sodium undergo close monitoring of serum sodium.

Liver Injury: SAMSCA can cause serious and potentially fatal liver injury. In a placebo-controlled and open label extension study of chronically administered tolvaptan in patients with autosomal dominant polycystic kidney disease, cases of serious liver injury attributed to tolvaptan were observed. An increased incidence of ALT greater than three times the upper limit of normal was associated with tolvaptan (42/958 or 4.4%) compared to placebo (5/484 or 1.0%). Cases of serious liver injury were generally observed starting 3 months after initiation of tolvaptan although elevations of ALT occurred prior to 3 months. Patients with symptoms that may indicate liver injury, including fatigue, anorexia, right upper abdominal discomfort, dark urine or jaundice should discontinue treatment with SAMSCA. Limit duration of therapy with SAMSCA to 30 days. Avoid use in patients with underlying liver disease, including cirrhosis, because the ability to recover from liver injury may be impaired. **Dehydration and Hypovolemia:** SAMSCA therapy induces copious aquaresis, which is normally partially offset by fluid intake. Dehydration and hypovolemia can occur, especially in potentially to upper debo-controlled trials in which 607 hyponatremic patients were treated with tolvaptan, the incidence of dehydration was 3.3% for tolvaptan and 1.5% for placebo-treated patients. In patients receiving SAMSCA who develop medically significant signs or symptoms of hypovolemia, interrupt or discontinue SAMSCA therapy and provide supportive care with careful management of vital signs, fluid balance and electrolytes. Fluid restriction during

therapy with SAMSCA may increase the risk of dehydration and hypovolemia. Patients receiving SAMSCA should continue ingestion of fluid in response to thirst. **Co-administration with Hypertonic Saline:** Concomitant use with hypertonic saline is not recommended. **Drug Interactions:** 

Other Drugs Affecting Exposure to Tolvaptan:

*CYP 3A Inhibitors:* Tolvaptan is a substrate of CYP 3A. CYP 3A inhibitors can lead to a marked increase in tolvaptan concentrations. Do not use SAMSCA with strong inhibitors of CYP 3A and avoid concomitant use with moderate CYP 3A inhibitors.

*CYP 3A Inducers:* Avoid co-administration of CYP 3A inducers (e.g., rifampin, rifabutin, rifapentin, barbiturates, phenytoin, carbamazepine, St. John's Wort) with SAMSCA, as this can lead to a reduction in the plasma concentration of tolvaptan and decreased effectiveness of SAMSCA treatment. If co-administered with CYP 3A inducers, the dose of SAMSCA may need to be increased.

*P-gp Inhibitors:* The dose of SAMSCA may have to be reduced when SAMSCA is co-administered with P-gp inhibitors, e.g., cyclosporine.

Hyperkalemia or Drugs that Increase Serum Potassium: Treatment with tolvaptan is associated with an acute reduction of the extracellular fluid volume which could result in increased serum potassium. Serum potassium levels should be monitored after initiation of tolvaptan treatment in patients with a serum potassium  $>5~{\rm mEq/L}$  as well as those who are receiving drugs known to increase serum potassium levels.

#### ADVERSE REACTIONS:

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reactions rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse event information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates. In multiple-dose, placebo-controlled trials, 607 hyponatremic patients (serum sodium <135 mEq/L) were treated with SAMSCA. The mean age of these patients was 62 years; 70% of patients were male and 82% were Caucasian. One hundred eighty-nine (189) tolvaptantreated patients had a serum sodium <130 mEq/L, and 52 patients had a serum sodium <125 mEq/L. Hyponatremia was attributed to cirrhosis in 17% of patients, heart failure in 68% and SIADH/other in 16%. Of these patients, 223 were treated with the recommended dose titration (15 mg titrated to 60 mg as needed to raise serum sodium). Overall, over 4,000 patients have been treated with oral doses of tolvaptan in open-label or placebo-controlled clinical trials. Approximately 650 of these patients had hyponatremia; approximately 219 of these hyponatremic patients were treated with tolvaptan for 6 months or more. The most common adverse reactions (incidence  $\geq 5\%$  more than placebo) seen in two 30-day, double-blind. placebo-controlled hyponatremia trials in which tolvaptan was administered in titrated doses (15 mg to 60 mg once daily) were thirst, dry mouth, asthenia constipation, pollakiuria or polyuria and hyperglycemia. In these trials, 10% (23/223) of tolvaptan-treated patients discontinued treatment because of an adverse event, compared to 12% (26/220) of placebo-treated patients; no adverse reaction resulting in discontinuation of trial medication occurred at an incidence of >1% in tolvaptantreated patients.

Table 1 lists the adverse reactions reported in tolvaptan-treated patients with hyponatremia (serum sodium <135 mEq/L) and at a rate at least 2% greater than placebo-treated patients in two 30-day, double-blind, placebo-controlled trials. In these studies, 223 patients were exposed to tolvaptan (starting dose 15 mg, titrated to 30 and 60 mg as needed to raise serum sodium). Adverse events resulting in death in these trials were 6% in tolvaptan-treated-patients and 6% in placebo-treated patients.

Table 1. Adverse Reactions (>2% more than placebo) in Tolvaptan-Treated Patients in Double-Blind, Placebo-Controlled Hyponatremia Trials

System Organ Class MedDRA Preferred Term	Tolvaptan 15 mg/day-60 mg/day (N = 223); n (%)	Placebo (N = 220); n (%)		
Gastrointestinal Disorders				
Dry mouth	28 (13)	9 (4)		
Constipation	16 (7)	4 (2)		
General Disorders and Administration Site Conditions				
Thirst <sup>a</sup>	35 (16)	11 (5)		
Asthenia	19 (9)	9 (4)		
Pyrexia	9 (4)	2 (1)		
Metabolism and Nutrition Disorders				
Hyperglycemia <sup>b</sup>	14 (6)	2 (1)		
Anorexia <sup>c</sup>	8 (4)	2 (1)		
Renal and Urinary Disorders				
Pollakiuria or polyuria <sup>d</sup>	25 (11)	7 (3)		

The following terms are subsumed under the referenced ADR in Table 1: <sup>a</sup>polydipsia; <sup>b</sup>diabetes mellitus; <sup>c</sup>decreased appetite; <sup>d</sup>urine output increased, micturition urgency, nocturia

In a subgroup of patients with hyponatremia (N = 475, serum sodium <135 mEq/L)

events occurred in 18% of the patients at 1 month. Additional safety and efficacy data, along with plans for postmarket surveillance, will be needed prior to approval for clinical use.

Are there other options to obtain hemostasis? Clotting factor products, specifically fresh frozen plasma (FFP) and prothrombin complex concentrates (PCCs), are often used to attempt to reverse anticoagulation from DOACs. While FFP alone has no evidence to support its use in reversing the effect of DOACs, PCCs might reverse anticoagulation for both Xa inhibitors and direct thrombin inhibitors.<sup>13</sup> Some experts recommend unactivated PCC over activated PCC because of a theoretically increased thrombotic risk of activated PCC.<sup>14</sup> For patients taking Xa inhibitors or dabigatran (if idarucizumab is unavailable) with life-threatening bleeding, PCC should be used in an attempt to reverse the bleeding.

Another strategy to promote hemostasis in bleeding patients taking DOACs is to use antifibrinolytics. Effective for control of bleeding in trauma and surgical patients, tranexamic acid has not been widely studied in nonsurgical bleeding, much less DOAC-related nonsurgical bleeding. A 2014 Cochrane review of a small number of trials suggested a possible mortality benefit from its use in upper GI bleeding, but the quality of included trials was poor.<sup>15</sup> The ongoing HALT-IT trial, enrolling 8,000 patients with gastrointestinal bleeding, aims to clarify the mortality benefit of tranexamic acid.<sup>16</sup> Despite effectively promoting hemostasis in many populations of bleeding patients, tranexamic acid carries no discernible thrombotic risk.<sup>17,18</sup> By preventing clot degradation through a downstream mechanism at low cost and risk, antifibrinolytics are a practical adjunctive therapy to control major bleeding in patients on DOACs.

Can charcoal or dialysis reduce the systemic concentration of DOACs?

In addition to discontinuing the DOAC,

#### SAMSCA® (tolvaptan)

enrolled in a double-blind, placebo-controlled trial (mean duration of treatment was 9 months) of patients with worsening heart failure, the following adverse reactions occurred in tolvaptan-treated patients at a rate at least 2% greater than placebo: mortality (42% tolvaptan, 38% placebo), nausea (21% tolvaptan, 16% placebo), thirst (12% tolvaptan, 2% placebo), dry mouth (7% tolvaptan, 2% placebo) and polyuria or pollakiuria (4% tolvaptan, 1% placebo).

Gastrointestinal bleeding in patients with cirrhosis: In patients with cirrhosis treated with tolvaptan in the hyponatremia trials, gastrointestinal bleeding was reported in 6 out of 63 (10%) tolvaptan-treated patients and 1 out of 57 (2%) placebo treated patients. The following adverse reactions occurred in <2% of hyponatremic patients treated with SAMSCA and at a rate greater than placebo in double-blind placebo-controlled trials (N = 607 tolvaptan; N = 518 placebo) or in <2% of patients in an uncontrolled trial of patients with hyponatremia (N = 111) and are not mentioned elsewhere in the label: Blood and Lymphatic System Disorders: Disseminated intravascular coagulation; Cardiac Disorders: Intracardiac thrombus, ventricular fibrillation; Investigations: Prothrombin time prolonged; Gastrointestinal Disorders: Uschemic colitis; Metabolism and Nutrition Disorders: Urethral hemorrhage; Reproductive System and Breast Disorders: Pulmonary embolism, respiratory failure; Vascular disorder: Deep vein thrombosis.

**Postmarketing Experience:** The following adverse reactions have been identified during post-approval use of SAMSCA. Because these reactions are reported voluntarily from a population of an unknown size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

*Neurologic:* Osmotic demyelination syndrome; Investigations: Hypernatremia. Removal of excess free body water increases serum osmolality and serum sodium concentrations. All patients treated with tolvaptan, especially those whose serum sodium levels become normal, should continue to be monitored to ensure serum sodium remains within normal limits. If hypernatremia is observed, management may include dose decreases or interruption of tolvaptan treatment, combined with modification of free-water intake or infusion. During clinical trials of hyponatremic patients, hypernatremia was reported as an adverse event in 0.7% of patients receiving tolvaptan vs. 0.6% of patients receiving placebo; analysis of laboratory values demonstrated an incidence of hypernatremia of 1.7% in patients receiving tolvaptan vs. 0.8% in patients receiving placebo. *Immune System Disorders:* Hypersensitivity reactions including anaphylactic shock and rash generalized. **DRUG INTERACTIONS:** 

#### Effects of Drugs on Tolvaptan:

Ketoconazole and Other Strong CYP 3A Inhibitors: SAMSCA is metabolized primarily by CYP 3A. Ketoconazole is a strong inhibitor of CYP 3A and also an inhibitor of P-gp. Co-administration of SAMSCA and ketoconazole 200 mg daily results in a 5-fold increase in exposure to tolvaptan. Co-administration of SAMSCA with 400 mg ketoconazole daily or with other strong CYP 3A inhibitors (e.g., clarithromycin, itraconazole, telithromycin, saquinavir, nelfinavir, ritonavir and nefazodone) at the highest labeled dose would be expected to cause an even greater increase in tolvaptan exposure. Thus, SAMSCA and strong CYP 3A inhibitors should not be co-administered. **Moderate CYP 3A Inhibitors:** The impact of moderate CYP 3A inhibitors (e.g., erythromycin, fluconazole, aprepitant, diltiazem and verapamil) on the exposure to co-administered tolvaptan has not been assessed. A substantial increase in the exposure to tolvaptan would be expected when SAMSCA with moderate CYP 3A inhibitors should therefore generally be avoided. **Grapefruit Juice:** Co-administered tolvaptan. **P-gp Inhibitors:** Reduction in the dose of SAMSCA may be required in patients concomitantly treated with P-gp inhibitors, such as e.g., cyclosporine, based on clinical response. **Rifampin and Other CYP 3A Inducers:** Rifampin is an inducer of CYP 3A and P-gp. Co-administration of rifampin and SAMSCA reduces exposure to tolvaptan by 85%. Therefore, the expected clinical effects of SAMSCA in the presence of rifampin and other inducers (e.g., rifabutin, rifapentin, barbiturates, phenytoin, carbamazepine and St. John's Wort) may not be observed at the usual dose levels of SAMSCA. The dose of SAMSCA may have to be increased. **Lovastatin, Digoxin, Furosemide, and Hydrochlorothiazide:** Co-administration of lovastatin, digoxin, furosemide, and hydrochlorothiazide: Co-administration of lovastatin, digoxin, furosemide, and hydrochlorothiazide with SAMSCA has no clinically relevant impact on the exposure to tolvaptan.

Effects of Tolvaptan on Other Drugs: Digoxin: Digoxin is a P-gp substrate. Co-administration of SAMSCA with digoxin increased digoxin AUC by 20% and Cmax by 30%. Warfarin, Amiodarone, Furosemide, and Hydrochlorothiazide: Co-administration of tolvaptan does not appear to alter the pharmacokinetics of warfarin, furosemide, hydrochlorothiazide, or amiodarone (or its active metabolite, desethylamiodarone) to a clinically significant degree. Lovastatin: SAMSCA is a weak inhibitor of CYP 3A. Co-administration of lovastatin and SAMSCA increases the exposure to lovastatin and its active metabolite lovastatin-β hydroxyacid by factors of 1.4 and 1.3, respectively. This is not a clinically relevant change.

Pharmacodynamic Interactions: Tolvaptan produces a greater 24 hour urine volume/excretion rate than does furosemide or hydrochlorothiazide. Concomitant administration of tolvaptan with furosemide or hydrochlorothiazide results in a 24 hour urine volume/excretion rate that is similar to the rate after tolvaptan administration alone. Although specific interaction studies were not performed, in clinical studies tolvaptan was used concomitantly with beta-blockers, angiotensin receptor blockers, angiotensin converting enzyme inhibitors and potassium sparing diuretics. Adverse reactions of hyperkalemia were approximately 1-2% higher when tolvaptan was administered with angiotensin receptor blockers, angiotensin converting enzyme inhibitors and potassium sparing converting enzyme inhibitors and potassium sparing diuretics compared to administration of these medications with placebo. Serum potassium levels should be

monitored during concomitant drug therapy. As a V<sub>2</sub>-receptor antagonist, tolvaptan may interfere with the V<sub>2</sub>-agonist activity of desmopressin (dDAVP). In a male subject with mild Von Willebrand (vW) disease, intravenous infusion of dDAVP 2 hours after administration of oral tolvaptan did not produce the expected increases in vW Factor Antigen or Factor VIII activity. It is not recommended to administer SAMSCA with V<sub>2</sub>-agonist.

USE IN SPECIFIC POPULATIONS: There is no need to adjust dose based on age, gender, race, or cardiac function.

**Pregnancy:** Pregnancy Category C. There are no adequate and well controlled studies of SAMSCA use in pregnant women. In animal studies, cleft palate, brachymelia, microphthalmia, skeletal malformations, decreased fetal weight, delayed fetal ossification, and embryo-fetal death occurred. SAMSCA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In embryo-fetal development studies, pregnant rats and rabbits received oral tolvaptan during organogenesis. Rats received 2 to 162 times the maximum recommended human dose (MRHD) of tolvaptan (on a body surface area basis). Reduced fetal weights and delayed fetal ossification occurred at 162 times the MRHD. Signs of maternal toxicity (reduction in body weight gain and food consumption) occurred at 16 and 162 times the MRHD. When pregnant rabbits received oral tolvaptan at 32 to 324 times the MRHD (on a body surface area basis), there were reductions in maternal body weight gain and food consumption at all doses, and increased abortions at the mid and high doses (about 97 and 324 times the MRHD). At 324 times the MRHD, there were increased rates of embryo-fetal death, fetal microphthalmia, open eyelids, cleft palate, brachymelia and skeletal malformations.

Labor and Delivery: The effect of SAMSCA on labor and delivery in humans is unknown. Nursing Mothers: It is not known whether SAMSCA is excreted into human milk. Tolvaptan is excreted into the milk of lactating rats. Because many drugs are excreted into human milk and because of the potential for serious adverse reactions in nursing infants from SAMSCA, a decision should be made to discontinue nursing or SAMSCA, taking into consideration the importance of SAMSCA to the mother. Pediatric Use: Safety and effectiveness of SAMSCA in pediatric patients have not been established.

Geriatric Use: Of the total number of hyponatremic subjects treated with SAMSCA in clinical studies, 42% were 65 and over, while 19% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Increasing age has no effect on tolvaptan plasma concentrations.

**Use in Patients with Hepatic Impairment:** Moderate and severe hepatic impairment do not affect exposure to tolvaptan to a clinically relevant extent. Avoid use of tolvaptan in patients with underlying liver disease.

Use in Patients with Renal Impairment: No dose adjustment is necessary based on renal function. There are no clinical trial data in patients with CrCl <10 mL/min, and, because drug effects on serum sodium levels are likely lost at very low levels of renal function, use in patients with a CrCl <10 mL/min is not recommended. No benefit can be expected in patients who are anuric.

Use in Patients with Congestive Heart Failure: The exposure to tolvaptan in patients with congestive heart failure is not clinically relevantly increased. No dose adjustment is necessary.

**OVERDOSAGE:** Single oral doses up to 480 mg and multiple doses up to 300 mg once daily for 5 days have been well tolerated in studies in healthy subjects. There is no specific antidote for tolvaptan intoxication. The signs and symptoms of an acute overdose can be anticipated to be those of excessive pharmacologic effect: a rise in serum sodium concentration, polyuria, thirst, and dehydration/hypovolemia. The oral LD<sub>50</sub> of tolvaptan in rats and dogs is >2000 mg/kg. No mortality was observed in rats or dogs following single oral doses of 2000 mg/kg (maximum feasible dose). A single oral dose of 2000 mg/kg was lethal in mice, and symptoms of toxicity in affected mice included decreased locomotor activity, staggering gait, tremor and hypothermia.

If overdose occurs, estimation of the severity of poisoning is an important first step. A thorough history and details of overdose should be obtained, and a physical examination should be performed. The possibility of multiple drug involvement should be considered.

Treatment should involve symptomatic and supportive care, with respiratory, ECG and blood pressure monitoring and water/electrolyte supplements as needed. A profuse and prolonged aquaresis should be anticipated, which, if not matched by oral fluid ingestion, should be replaced with intravenous hypotonic fluids, while closely monitoring electrolytes and fluid balance.

ECG monitoring should begin immediately and continue until ECG parameters are within normal ranges. Dialysis may not be effective in removing tolvaptan because of its high binding affinity for human plasma protein (>99%). Close medical supervision and monitoring should continue until the patient recovers.

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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both charcoal and dialysis can reduce the systemic concentration of DOACs. If the ingestion was recent, oral activated charcoal can reduce the systemic absorption of DOACs. To date there are no data on the efficacy of charcoal in bleeding patients taking DOACs. However, in two recent trials, administration of a single dose of charcoal in healthy patients led to significantly decreased area under concentrationtime curves (AUC) when given at 6 and 8 hours after ingestion of a therapeutic dose of apixaban and rivaroxaban, respectively.<sup>19,20</sup> While further studies are needed to confirm its clinical benefit, charcoal is recommended for major bleeding when given within 2 hours of ingestion of a DOAC and may be useful within 8 hours.

Unlike charcoal, which can be used for patients on Xa inhibitors or dabigatran, hemodialysis is only effective for reducing serum concentrations of dabigatran because of its low plasma protein binding (~35%). A review of 35 patients (10 with normal renal function) with severe bleeding showed significant reductions in coagulation tests (aPTT, PT, TT) and dabigatran levels after hemodialysis.<sup>21</sup> For severe bleeding episodes particularly in patients with impaired renal function, providers should consider the use of continuous renal replacement therapy until clinical hemostasis is achieved.

#### What is the expert's opinion?

We asked one of our hematologists with expertise in DOACs for his opinion on this topic. Most patients with DOAC-associated bleeding can be managed with supportive care because of the short half-life of these agents in patients with reasonably preserved renal function. The main scenario for escalating therapy to PCC or idarucizumab is life-threatening bleeding, such as intracranial hemorrhage and gastrointestinal hemorrhage with hemodynamic instability. The threshold for use of idarucizumab for patients taking dabigatran with bleeding should be lower than PCCs because there is better evidence for clinical benefit with less risk.

Developing reversal agents continues to be costly, requiring extensive preclinical work and clinical trials that are difficult to do. Assuming that reversal agents become more affordable in the longer term, and safety profiles are better established, clinicians may eventually have a lower threshold for their use in a wider variety of bleeding episodes. Lastly, adverse outcomes often occur, not during the acute bleeding episode, but several weeks later in patients whose providers delay restarting anticoagulation. Thus, it is important to resume anticoagulant therapy as soon as it is safe to do so.

#### Back to the case

Our patient was given a 50-g suspension of oral activated charcoal, along with two doses of 1 g intravenous tranexamic acid 8 hours apart. He was typed and crossed for blood, and ultimately received 1 unit of packed red blood cells before stabilizing without other measures. His colonoscopy subsequently revealed a diverticular bleed with a visible vessel that was coagulated. He was discharged 2 days later after remaining clinically stable after colonoscopy.

CONTINUED ON PAGE 34

#### Bottom line

For the majority of bleeding patients on DOACs, supportive care with transfusions and local hemostatic interventions to control bleeding will likely be sufficient. Because of the short half-lives of DOACs, most patients do not require additional therapy (Table 2), and these patients actually have better outcomes from major bleeding episodes than patients taking VKAs. Antifibrinolytics should be a first-line prohemostatic therapy in major bleeding. Oral activated charcoal may be effective within 2-8 hours after ingestion for reduction of serum DOAC concentrations. Finally, in cases of life-threatening bleeding, idarucizumab can be used to reverse anticoagulation for patients taking dabigatran. When idarucizumab is unavailable, or for patients taking Xa inhibitors, PCC can be used. 🎞

Dr. Albert is clinical instructor of medicine

#### Table 2: Management of Bleeding Patients Taking DOACs Direct Thrombin Inhibitors (dabigatran) Xa inhibitors (apixaban, edoxaban, rivaroxaban)

#### Minor Bleeding

- Withhold DOAC Local hemostatic measures

#### Major Bleeding\*

- All of the above, AND
- Antifibrinolytic if bleeding persists
- Restore physiologic perfusion
- Charcoal if last dose within 2-8 hours • Transfusion indications:
- o Red blood cells: anemia
- o Platelets: antiplatelet agents or thrombocytopenia
- o Plasma: coagulopathy (dilution, DIC, liver failure), not for DOAC reversal

#### Life-threatening Bleeding\*\*

- All of the above, AND:
- Idarucizumab (confirm anticoagulant effect with thrombin time first)
- If idarucizumab is unavailable, use PCC
- Consider hemodialysis until hemostasis achieved, especially if patient in renal failure
- All of the above, AND:
- Unactivated PCC (if available and calibrated to specific Xa inhibitor, confirm anticoagulant effect with anti-Xa level)

\* Adapted from the International Society on Thrombosis and Hemostasis: bleeding with a fall in hemoglobin level  $\geq 2$  g/dL, OR bleeding leading to  $\geq 2$ units of PRBC transfused.<sup>21</sup> Clinicians should perform risk stratification of bleeding episodes using vital signs, laboratory results, the area of bleeding, and patient comorbidities.

\*\*Uncontrolled bleeding, OR symptomatic bleeding in a critical area or organ (such as intracranial, intraocular, intraspinal, retroperitoneal, pericardial, or intramuscular with compartment syndrome).

at University of Washington Medical Center in Seattle. Dr. Garcia is professor of medicine and associate medical director of antithrombotic therapy at UWMC. Dr. Hagan is chief medical resident at UWMC. Dr. Huang is an attending with the UWMC Medicine Consult Service and assistant clinical professor in the division of general internal medicine at the University of Washington.

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### Cancer the most common diagnosis in palliative care patients

#### By Richard Franki

ore than one-quarter of the patients in palliative care have a primary diagnosis of cancer, according to the Center to Advance Palliative Care.

A survey of 351 palliative care programs showed that 27% of their patients had been diagnosed with cancer in 2016, more than twice as many patients who had a cardiac (13%) or pulmonary (12%) diagnosis. The next most common primary diagnosis category in 2016 was neurologic at 8%, with a tie at 6% between diagnoses classified as infectious or complex chronic, followed by patients with dementia at 5%, Maggie Rogers and Tamara Dumanovsky, PhD, of the CAPC, reported.

By specialty, more than half of referrals to palliative care came from hospital medicine (53.5%), while 12% were referred by internal/family medicine, another 12% by pulmonary/critical care medicine, and 7% by oncology, Ms. Rogers and Dr. Dumanovsky said in their analysis of data from the CAPC's National Palliative Care Registry.

A medical/surgical unit was the referring site for 43% of palliative care referrals in 2016, with 26% of patients coming from an intensive care unit, 13% from a step-down unit, and 8% from an oncology unit, they noted.

#### Most common primary diagnosis categories



Note: Survey was completed by 351 adult or mixed adult/pediatric palliative care programs. Source: Center to Advance Palliative Care

### A passion for education: Lonika Sood, MD

#### Dr. Sood joins The Hospitalist Editorial Advisory Board

n top of her role as a hospitalist at the Aurora BayCare Medical Center in Green Bay, Wis., Lonika Sood, MD, CMPE, is currently a candidate for a masters in health professions education.

From her earliest training to the present day, she has maintained her passion for education, both as a student and an educator.

"I am a part of a community of practice, if you will, of other health professionals who do just this – medical education on a higher level," Dr. Sood said. "Not only on the front lines of care, but also in designing curricula, undertaking medical education research, and holding leadership positions at medical schools and hospitals around the world."

As one of the eight new members of *The Hospitalist* editorial advisory board, Dr. Sood is excited to use her role to help inform and to learn. She told us more about herself in a recent interview.

#### Q: How did you choose a career in medicine?

A: I grew up in India. I come from a family of doctors. When I was in high school, we found that we had close to 60 physicians in our family, and that number has grown quite a bit since then. At home, being around physicians, that was the language that I grew into. It was a big part of who I wanted to become when I grew up. The other part of it was that I've always wanted to help people and do something in one of the science fields, so this seemed like a natural choice for me.

#### Q: What made you choose hospital medicine?

A: I'll be very honest – when I came to the United States for my residency, I wanted to become a subspecialist. I used to joke with my mentors in my residency program that every month I wanted to be a different subspecialist depending on which rotation I had or which physician really did a great job on the wards. After moving to Rochester, N.Y., for personal reasons, I said, "We'll keep residency on hold for a couple of years." Then I realized that I really liked medical education. I knew I wanted something where I could fulfill my desire to be a specialist by being a medical educator, yet keep practicing internal medicine, which is something that I've always wanted to do. Being a hospitalist is like a marriage of those two passions.

#### Q: What about medical education draws you?

A: I think a large part of it was that my mother is a physician. My dad is in the merchant navy. In their midlife, they kind of fine-tuned their career paths by going into teaching, so both of them are educators, and very well accomplished in their own right. Growing up, that was a big part of what I saw myself becoming. I did not realize until later in my residency that it was my calling. Additionally, my experience of going into medicine and learning from good teachers is, in my mind, one of the things that really makes me comfortable, and happy being a doctor. I want to be able to leave that legacy for the coming generation.

### Q: Tell us how your skills as a teacher help you when you're working with your patients?

A: To give you an example, we have an adult internal medicine hospital, so we frequently have patients who come to the hospital for the first time. Some of our patients have not seen a physician in over 30 or 40 years. There may be many reasons for that, but they're scared. They're sick. They're in a new environment. They are placing their trust in somebody else's hands. As teachers and as doctors, it's important for us to be compassionate, kind, and relatable to patients. We must also be able to explain to patients in their own words what is going on with their body, what might happen, and how can we help. We're not telling patients what to do or forcing them to take our treatment recommendations, but we are helping them make informed choices. I think hospital medicine really is an incredibly powerful field that can help us relate to our patients.

### Q: What is the best professional advice you have received in medicine?

A: I think the advice that I try to follow every day is to be humble. Try to be the best that you can be, yet stay humble, because there's so much more that you can accomplish if you stay grounded. I think that has stuck with me. It's come from my parents. It's come from my mentors. And sometimes, it comes from my patients, too.

#### Q: What is the worst advice you have received?

A: That's a hard question, but an important one as well, I think. Sometimes, there is a push – from society or your colleagues – to be as efficient as you can be, which is great,



but we have to look at the downside of it. We sometimes don't stop and think, or stop and be human. We're kind of mechanical if data are all we follow.

#### Q: So where do you see yourself in the next 10 years?

A: That's a question I try to answer daily, and I get a different answer each time. I think I do see myself continuing to provide clinical care for hospitalized patients. I see myself doing a little more in educational leadership, working with medical students and medical residents. I'm just completing my master's in health professions education, so I'm excited to also start a career in medical education research.

#### Q: What's the best book that you've read recently, and why was it the best?

A: Oh, well, it's not a new book, and I've read this before, but I keep coming back to it. I don't know if you've heard of Jim Corbett. He was a wildlife enthusiast in the early-20th century. He wrote a lot of books on man-eating tigers and leopards in India.



Dr. Lonika Sood, a hospitalist based at Aurora BayCare Medical Center, Green Bay, Wis.

My brother and I and my dad used to read these books growing up. That's something that I'm going back to and rereading. There is a lot of rich description about Indian wildlife, and it's something that brings back good memories.



#### **CLINICAL**



### **ITL:** Physician reviews of HM-centric research

By Jeremiah Newsom, MD, MSPH; Luis Teixeira, MD; Ella Choe, MD, FHM; Emily Ramee, MD; Steven Deitelzweig, MD, MMM, SFHM

Department of Hospital Medicine, Ochsner Health System, New Orleans

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- 8. Behavioral approach to appropriate antimicrobial prescribing in hospitals

By Jeremiah Newsom, MD, MSPH

#### Hospital-acquired anemia **CLINICAL QUESTION:** Is hospital

acquired anemia associated with increased postdischarge adverse outcomes?

**BACKGROUND:** Hospital acquired anemia (HAA) is defined as the development of anemia during the course of a hospitali-

zation when starting with a normal hemoglobin on admission. The incidence of HAA is at least 25% when using the last hemoglobin prior to discharge as the index value. HAA is felt to be poten- Dr. Newsom tially preventable and



usually iatrogenic due to phlebotomy. **STUDY DESIGN:** Observational cohort study.

**SETTING:** Six northern Texas hospitals.

**SYNOPSIS:** There were 11,309 index hospitalizations with a median hematocrit value on admission of 40.6 g/dL. The authors defined HAA as a normal hematocrit value within the first 24 hours of admission and a hematocrit value lower than the WHO sex-specific cut points at the time of discharge: mild HAA (hematocrit greater than 33% and less than 36% in women, greater than 33% and less than 40% in men), moderate HAA (greater than 27% and less than 33%). and severe HAA (less than 27%). Mild HAA occurred in 21.6% of patients, with 10.1% of patients developing moderate HAA, and 1.4% developing severe HAA (85% underwent major procedure, diagnosis of hemorrhage or coagulation/hemorrhagic disorder). Predictors of developing moderate/severe HAA included undergoing a major diagnostic or therapeutic procedure, female sex, elective admission, hospital LOS, BUN to creatinine ratio greater than 20:1, and serum creatinine on admission. Development of severe HAA was associated with a 41% increase in the odds of 30-day readmission and a 39% increase in the odds of the composite outcome (30-day mortality and 30-day readmission).

**BOTTOM LINE:** Severe HAA had significant increased odds of 30-day readmission and mortality, but might not be as preventable as initially thought given the frequency of major procedures and hemorrhage in those that developed severe HAA.

CITATION: Makam AN, Nguyen OK, Clark C, Halm EA. Incidence, predictors, and outcomes of hospital-acquired anemia. J Hosp Med. 2017;12(5):317-22.

#### **2** Impact of elder program on delirium and LOS for abdominal surgery patients

**CLINICAL QUESTION:** Can a modified Hospital Elder Life Program (mHELP) reduce delirium and hospital LOS in older patients undergoing abdominal surgery? **BACKGROUND:** Development of delirium in the hospitalized patient, especially postsurgical patients, can have detrimental effects on the clinical recovery and LOS. Delirium occurs in 13%-50% of patients undergoing noncardiac surgery, and older surgical patients are at a higher risk.

STUDY DESIGN: Cluster randomized clinical trial. SETTING: A 2,000-bed urban medical

center in Taipei, Taiwan.

SYNOPSIS: There were 377 older patients (65 years of age or older) who were admitted for elective abdominal surgery (gastrectomy, pancreaticoduodenectomy, or colectomy) with an expected LOS greater than 6 days enrolled and randomly assigned to mHELP group (197 patients) or control group (180 patients). The mHELP intervention consisted of three core nursing protocols that occurred daily by a trained

nurse: orienting communication, oral and nutritional assistance, and early mobilization. Delirium developed in 13 cases (6.6%) in the mHELP group and in 27 cases (15.1%) in the control group. This is a risk reduction of 56% indicating the need to treat 11.8 patients to prevent one case of delirium. The mHELP group had a 2-day hospital LOS reduction, compared with the control group. The effect of mHELP could be underestimated as crossover effects were not accounted for in the study. Data were not collected on postoperative complications which can have a significant effect on delirium occurrence.

**BOTTOM LINE:** The three nursing protocols of mHELP reduced rates of delirium and hospital LOS in older adults undergoing abdominal surgeries and could be a quick intervention to reduce the most common surgical complication in older patients.

CITATION: Chen CC, Li HC, Liang JT, et al. Effect of a modified hospital elder life program on delirium and length of hospital stay in patients undergoing abdominal surgery. JAMA Surg. Published online May 24, 2017. doi: 10.1001/jamasurg.2017.1083.

Dr. Newsom is a hospitalist at Ochsner Health System, New Orleans.

By Luis Teixeira, MD

#### Bowel rest or early feeding for **J** acute pancreatitis

**CLINICAL QUESTION:** When should you start enteral feedings in patients with acute pancreatitis?

**BACKGROUND:** Oral intake stimulates pancreatic exocrine activity and therefore bowel rest has been

one of the mainstays of acute pancreatitis treatment. However, some studies suggest that enteral nutrition may reduce the risk of infection by supporting the gut's protective barrier limiting Dr. Teixeira bacterial transloca-

tion and sepsis. Studies thus far comparing early versus delayed enteral nutrition in acute pancreatitis have been conflicting. **STUDY DESIGN:** Systematic review.

SETTING: Europe, New Zealand, United States, and China.

SYNOPSIS: Study authors attempted to compare the length of hospital stay, mortality, and readmission in hospitalized patients with acute pancreatitis who received early versus delayed feeding. The authors searched for randomized clinical

trials that compared early feeding (less than 48 hours after hospitalization) versus delayed feeding (more than 48 hours after hospitalization).

The authors found and analyzed 11 randomized trials comprising 948 patients in which early and delayed feeding strategies were compared. Their review suggests that early feeding in patients with acute pancreatitis is not associated with increased adverse events and may reduce length of hospital stay. Their analysis was limited by markedly different feeding protocols that precluded performing a meta-analysis. Their analysis was also limited by including studies that had high risk or unclear risk of bias and by the small size of most trials limiting power to detect differences in outcome.

**BOTTOM LINE:** Optimal route and timing of nutrition in patients with acute pancreatitis remains unsettled.

CITATION: Vaughn VM, Shuster D, Rogers MAM, et al. Early versus delayed feeding in patients with acute pancreatitis: a systematic review. Ann Intern Med. 2017;166(12):883-92.

#### **4** Anticoagulation for patients with liver cirrhosis and portal vein thrombosis

**CLINICAL QUESTION:** Should patients with liver cirrhosis with portal vein thrombosis be treated with anticoagulation?

BACKGROUND: Portal vein thrombosis occurs in about 20% of patients with liver cirrhosis. Previously these patients were not often treated with anticoagulation due to concern for increased bleeding risk associated with advanced liver disease. However, restoring portal vein patency may prevent further sequelae, including intestinal infarction and portal hypertension and may also affect candidacy for liver transplantation.

**STUDY DESIGN:** Meta-analysis.

**SETTING:** Multiple sites throughout the world.

SYNOPSIS: The authors of this meta-analysis pooled data from eight clinical trials, comprising 353 patients with liver cirrhosis and portal vein thrombosis, to assess the rates of complete and partial recanalization with anticoagulation therapy (warfarin or low molecular weight heparin) versus no therapy. The authors also assessed the rate of minor and major bleeding complications in patients who received anticoagulation, compared with those who received no therapy. Patients who received anticoagulation therapy had increased recanalization and CONTINUED ON PAGE 38

reduced progression of thrombosis without excessive major and minor bleeding.

**BOTTOM LINE:** This meta-analysis suggests anticoagulation might be safe and effective in treating portal vein thrombosis in patients with cirrhosis; however, this analysis was based on nonrandomized clinical trials and did not address long-term important endpoints, such as the effect of anticoagulation on mortality.

**CITATION:** Loffredo L, Pastori D, Farcomeni A, Violi F. Effects of anticoagulants in patients with cirrhosis and portal vein thrombosis: A systematic review and metaanalysis. Gastroenterology. 2017 May 4. E-published ahead of print.

Dr. Teixeira is a hospitalist at Ochsner Health System, New Orleans.

By Ella Choe, MD, FHM

#### **5** Sepsis time to treatment CLINICAL QUESTION: Does early iden-

CLINICAL QUESTION: Does early identification and treatment of sepsis using protocols improve outcomes?

**BACKGROUND:** International clinical guidelines recommend early detection and treatment of sepsis with broad-spectrum antibiotics and intravenous fluids which are supported by preclinical and observation studies that show a reduction in avoidable deaths. However, controversy

remains in the timing of these treatments on how it relates to patient outcomes such as risk-adjusted

mortality. **STUDY DESIGN:** Retrospective cohort study using data reported to the New York State Department of Health from April 1, 2014, to June

30, 2016. Dr. Choe SETTING: New York hospitals.

**SYNOPSIS:** For patients with sepsis and septic shock, a sepsis protocol was initiated within 6 hours after arrival in the emergency department and had all items in a 3-hour bundle of care completed within 12 hours (that is, blood cultures, broad-spectrum antibiotic, and lactate measurement). Among 49,331 patients at 149 hospitals, higher risk-adjusted, in-hospital mortality was associated with longer time to the completion of the bundle (*P* less than .001), administration of antibiotics (*P* less than .001), but not completion of a bolus of intravenous fluids (*P* = .21).

Study limitations include being nonrandomized, hospitals all from one state possibly introducing epidemiologic distinct features of sepsis inherent to the region, and accuracy of the data collection (that is, start time). No association was found between time to completion of the initial bolus of fluids and improved outcomes in risk-adjusted mortality; however, the analysis of time of the initial fluid bolus was most vulnerable to confounding. A causal relationship will need further study.

**BOTTOM LINE:** A lower risk-adjusted in-hospital mortality was associated with rapid administration of antibiotics and a faster completion of a 3-hour bundle of sepsis care, but there was no discernible association with the rapid administration of initial bolus of intravenous fluids. **CITATION:** Seymour CW, Gesten F, Prescott HC, et al. Time to treatment and mortality

during mandated emergency care for sepsis. N Engl J Med. 2017; 376:2235-44.

#### **6** Use of BZD and sedative-hypnotics among hospitalized elderly

**CLINICAL QUESTION:** Which hospitalized older patients are inappropriately prescribed benzodiazepines or sedative hypnotics post discharge, and who is prescribing these medications?

**BACKGROUND:** During hospitalization, older patients commonly suffer from agitation and insomnia. Unfortunately, benzodiazepines and sedative hypnotics are commonly used as first-line treatments for these conditions despite significant risk that includes cognitive impairment, postural

#### SHORT TAKES

Intervention to reduce broad-spectrum antibiotics and treatment durations prescribed at the time of hospital discharge: A novel stewardship approach

This retrospective cohort study at Denver Health (urban, academic center) is the first description in the literature of an antibiotic stewardship intervention designed to optimize oral antibiotics at the time of discharge. Their multifaceted intervention to optimize antibiotic prescribing was associated with less frequent use of antibiotics with broad gram-negative activity and shorter treatment durations.

Citation: Yogo N, Shihadeh K, Young H, et al. Intervention to reduce broad-spectrum antibiotics and treatment durations prescribed at the time of hospital discharge: A novel stewardship approach. Infect Control Hosp Epidemiol. 2017 May;38(5)534-41.

instability, increased risk of falls and hip fracture, as well as lack of effectiveness.



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The purpose of this study is to determine the magnitude of the issue, discover root causes, and determine the type or types of corrective action needed.

**STUDY DESIGN:** Single-center retrospective observational study.

**SETTING:** Urban academic medical center in Toronto.

**SYNOPSIS:** Patient- and prescriber-level variables were identified and associated with potentially inappropriate newly prescribed benzodiazepine or sedative-hypnotics to medical-surgical inpatients aged 65 or older (regular users were excluded), which amounted to 208 patients of the 1,308 patients studied. The majority of the indications were for insomnia or agitation/anxiety prescribed overnight with 222 out of 1,308 patients (15.9%).

There was significant increase in these prescriptions if the patient was admitted to a surgical or specialty service, compared with the general internal medicine service (odds ratio, 6.61; 95% confidence interval, 2.70-16.17). First-year trainees prescribed these medications more than did attending or fellows (OR, 0.28; 95% CI, 0.08-0.93).

Study limitations include being from a single institution, not being blinded, and inadequate statistical power. Therefore, it may lack generalizability, may be subjected to observer bias, and may not detect significant effects of covariates.

**BOTTOM LINE:** Sleep disruption and poor quality of sleep were the primary reasons for the majority of potentially inappropriate new prescriptions of benzodiazepines and sedative hypnotics, with first-year trainees being more likely to prescribe these medications, compared with attendings and fellows.

**CITATION:** Pek EA, Ramfry A, Pendrith C, et al. High prevalence of inappropriate benzodiazepine and sedative hypnotic prescriptions among hospitalized older adults. J Hosp Med. 2017 May;12(5):310-6.

Dr. Choe is a hospitalist at Ochsner Health System, New Orleans.

#### By Emily Ramee, MD

### **7** Optimal empiric treatment for uncomplicated cellulitis

**CLINICAL QUESTION:** Is empiric MRSA coverage for nonpurulent cellulitis necessary?

**BACKGROUND:** Most nonpurulent skin and soft tissue infections are caused by beta-hemolytic streptococci and methicillin-susceptible *Staphylococcus aureus*. However, there is a growing incidence of community-acquired methicillin-resistant *S. aureus* infections. The authors of this study attempted to answer whether adding empiric methicillin-resistant *S. aureus* coverage reduces the risk of treatment failure.

**STUDY DESIGN:** Multicenter, double-blind, randomized superiority trial.

**SETTING:** Five emergency departments in the United States.

**SYNOPSIS:** The authors of this study randomized 500 patients with cellulitis without purulent drainage or evidence of abscess as confirmed by sonography to receive a 7-day course of either cephalexin with placebo or cephalexin plus trimethoprimsulfamethoxazole. When analyzing those patients who took most of the prescribed pills (greater than 75% of doses) according to treatment protocol, there was no significant difference in clinical cure rate between the two arms of the study, reaffirming current guidelines that advocate against empiric methicillin-resistant *S. aureus* coverage for uncomplicated cellulitis.

When the authors analyzed the result of their data with the assumption that patients who were lost to follow-up had treatment failure, there was a trend favoring the addition of trimethoprim-sulfamethoxazole with cephalexin over monotherapy with cephalexin (P = .07). Although the authors concluded that this finding may warrant further investigation, this was essentially a negative study.

**BOTTOM LINE:** Empirically adding community-acquired methicillin-resistant *S. aureus* coverage with trimethoprim-sulfamethoxazole to uncomplicated cellulitis did not statistically improve a clinical cure, compared with empiric treatment with monotherapy with cephalexin.

**CITATION:** Moran GJ, Krishnadasan A, Mower WR, et al. Effect of cephalexin plus trimethoprim-sulfamethoxazole vs. cephalexin alone on clinical cure of uncomplicated cellulitis. JAMA. 2017;317(20):2088-96.

#### Behavioral approach to appropriate antimicrobial prescribing in hospitals: The Dutch Unique Method for Antimicrobial Stewardship (DUMAS) participatory intervention study

**CLINICAL QUESTION:** How effective is an antimicrobial stewardship approach grounded in behavioral theory and focused on preserving prescriber autonomy and participation in improving appropriateness of antimicrobial prescribing in hospitals? **BACKGROUND:** Antimicrobial stewardship programs aim to achieve the goal of improv-

programs aim to achieve the goal of improving antimicrobial prescribing. This leads to significant benefits, including decreased antimicrobial resistance, improved clinical outcomes (lower morbidity and mortality), and lower health care costs. Stewardship programs do not often focus on the human behavior element of the prescribing physicians. Changing antimicrobial prescribing is a complex behavioral process, and there is a known persistent resistance between prescribers and the stewardship team. In a simple sense, this resistance is generated by tension created when prescribers do not have autonomy.

Previous studies that used interventions based on behavioral theory found promising results, but none of them were in a hospital setting. Rather, most of these studies had a narrow focus of respiratory tract infections in outpatient clinics.

**STUDY DESIGN:** Prospective, steppedwedge, participatory intervention study. **SETTING:** Seven clinical departments (two medical, three surgical, and two pediatric) in a tertiary care medical center and a general teaching hospital, both in Amsterdam. The first hospital was a 700-bed tertiary care center with salaried specialists, while the second hospital was a 550-bed general medical center with self-employed specialists.

SYNOPSIS: During a baseline period of 16 months and an intervention period of 12 months, physicians who prescribed systemic antimicrobial drugs for any indication were included in the study. In all, 1,121 patient cases with 700 prescriptions were studied during the baseline period and 882 patient cases with 531 prescriptions were studied during the intervention period. The intervention was as follows: Prescribers were offered a free choice of how to improve their antimicrobial prescribing. They were stimulated to choose interventions with higher potential for success based on a root cause analysis of inappropriate prescribing. The study was inspired by the participatory action research paradigm, which focuses on collaboration and empowerment of the stakeholders in the change process. In this study, prescribers were given reports of root cause analysis of their prior prescribing patterns. Then, they were invited to choose and codevelop one or more interventions that were tailored and individualized to improve their own prescribing. This approach draws on the following three behavioral principles: 1) respect for the prescriber's autonomy to avoid feelings of resistance; 2) the inclination that people have to value a product higher and feel more ownership of it if they made it themselves (the IKEA effect); 3) the tendency of people to follow up on an active and public commitment.

The primary outcome was antimicrobial appropriateness, measured with a validated appropriateness assessment instrument. One of three infectious disease specialists assessed the adult prescriptions, and one of three infectious disease/immunology pediatricians assessed the pediatric prescriptions for appropriateness. Appropriateness criteria were as follows: indication, choice of antimicrobial, dosage, route, and duration. A secondary outcome was antimicrobial consumption, reported as days of therapy per 100 admissions per month. Other outcomes were changes in specific appropriateness categories, intravenous antimicrobial consumption, consumption of specific antimicrobial subgroups, and length of hospital stay.

The mean antimicrobial appropriateness increased from 64.1% at intervention start to 77.4% at 12-month follow-up (+13.3%; relative risk, 1.17; 95% CI, 1.04-1.27), without a change in slope. Antimicrobial consumption remained the same during both study periods. Length of hospital stay did not change relative to the start of the intervention approach.

This is the first study of its kind, as a hospital antimicrobial stewardship program study grounded in behavioral science, with the key element being the free choice allowed to the prescribers, who made their own autonomous decisions about how to improve their prescribing. The authors hypothesize that the prescribers felt relatively nonthreatened by their approach since the prescribers maintained their free will to change their

own behavior if so desired. The prescribers were given a free intervention choice. For example, they could have just chosen "education" as an easy out; however, the root cause analysis seemed to be an impetus for the prescribers to choose interventions that would be more effective. A prior study in a nursing home setting was unsuccessful; aside from other differences, that study used a predetermined set of interventions, thus lacking the autonomy and IKEA effect seen in this study. **BOTTOM LINE:** Use of a behavioral approach that preserves prescriber autonomy resulted in an increase in antimicrobial appropriateness sustained for at least 12 months. The intervention is effective, inexpensive, and transferable to various health care settings. **CITATION:** Sikkens JJ, van Agtmael MA, Peters EJG, et al. Behavioral approach to appropriate antimicrobial prescribing in hospitals: The dutch unique method for antimicrobial stewardship (DUMAS) participatoryintervention study. JAMA Intern Med. Published online May 1, 2017. doi: 10.1001/jamainternmed.2017.0946. **III** 

Dr. Ramee is a hospitalist at Ochsner Health System, New Orleans.

#### SHORT TAKES

#### Hospital teaching status and mortality

Major teaching hospitals (members of the Council of Teaching Hospitals) have lower 30-day mortality rates when compared with nonteaching hospitals overall and for several of the top 15 medical DRGs based on review of hospitalizations for U.S. Medicare beneficiaries from 2012 through 2014. These differences persisted with adjustment for multiple hospital characteristics including volume and size.

Citation: Burke LG, Frakt AB, Khullar D, et al. Association between teaching status and mortality in US hospitals. JAMA. 2017;317(20):2105-13.

#### Predicting outcomes in ICU patients

Small prospective cohort study of 303 patients attempting to determine ICU physicians' and nurses' accuracy in predicting future survival and functional outcomes of critically ill patients at 6 months showing variability depending on the outcome predicted, but overall improved accuracy of the prediction coincident with higher levels of confidence in the predicted outcome. Citation: Detsky ME, Harhay MO, Bayard DF, et al. Discriminative accuracy of physician and nurse predictions for survival and functional outcomes 6 months after an ICU admission. JAMA. 2017;317(21):2187-95.

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**Contact:** Fayeann Hurley Schneck Medical Center Physician Recruitment 411 W Tipton St., Seymour, IN 47274 p: 812-523-7849 • c: 812-498-9500 www.schneckmed.org



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#### For additional information, please contact:

Brian Mc Gillen, MD — Director, Hospitalist Medicine Penn State Milton S. Hershey Medical Center c/o Heather Peffley, PHR FASPR - Physician Recruiter hpeffley@hmc.psu.edu



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Robert\_McCann@urmc.rochester.edu

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LEAD

HOSPITALIST

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Bassett Healthcare Network A.O. Fox Hospital

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For confidential consideration, please contact: Debra Ferrari, Manager, Medical Staff Recruitment Bassett Healthcare Network phone: 607-547-6982; fax: 607-547-3651 or email: debra.ferrari@bassett.org or for more information visit our web-site at www.bassett.org

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Please Contact: Tina McLaughlin, CMSR, Johnston Memorial Hospital Office (276) 258-4580, mclaughlint@msha.com



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Known for home of the Hershey chocolate bar, Hershey, PA is rich in history and offers a diverse culture. Our local neighborhoods boast a reasonable cost of living whether you prefer a more suburban setting or thriving city rich in theater, arts, and culture. Hershey, PA is home to the Hershey Bears hockey team and close to

the Harrisburg Senators baseball team. The Susquehanna River, various ski slopes and the Appalachian Trail are in our backyard, offering many outdoor activities for all seasons.



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The Penn State Milton S. Hershey Medical Center is committed to affirmative action, equal opportunity and the diversity of its workforce. Equal Opportunity Employer – Minorities/Women/Protected Veterans/Disabled.

Successful candidates require the following: • Medical degree - M.D., D.O. or foreign equivalent Completion of an accredited Internal Medicine Residency program
 Eligibility to acquire a license to practice in the Commonwealth of Pennsylvania • Board eligible/certified in Internal Medicine No J1 visa waiver sponsorships available

For further consideration, please send your CV to:

#### Brian McGillen, MD - Director, Hospital Medicine Penn State Milton S. Hershey Medical Center c/o Heather Peffley, PHR FASPR – Physician Recruiter hpefflev@hmc.psu.edu

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MEDICAL CENTER

#### **Hospital Medicine Faculty Positions**

The Section of Hospital Medicine at Vanderbilt University seeks talented BC/BE Internal Medicine physicians to join the full time faculty at the level of Assistant, Associate, or full Professor, on a clinical, academic, or research track.

Clinical positions, including daytime, nocturnist, extensivist or mixed roles, are available for well-trained physicians who wish to focus on direct patient care and medical consultation. We offer flexible scheduling, access to top specialists, and opportunities to engage in teaching, quality improvement, and scholarship. An academic clinicianeducator track position is 80% clinical, with additional responsibilities in teaching, scholarship, quality improvement, and administration for qualified candidates. A physicianscientist track provides 80% time for research in collaboration with established investigators in health services research, quality improvement, patient safety, behavioral sciences, and biomedical informatics.

Vanderbilt University Medical Center is a leader in providing high-quality, cost-effective care. With robust programs in quality improvement and clinical research, a highlydeveloped electronic health record, Magnet Recognition for nursing care, competitive salaries and benefits, and a highly supportive environment for faculty, Vanderbilt is a great place to work. With a booming economy and friendly environment, Nashville, TN is a top place to live.

Please electronically submit a letter of interest and CV to: anne.n.axon@vanderbilt.edu



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# Hospital Value-Based Purchasing is largely ineffective

How should hospitalist pay for performance change as a result?



Dr. Whitcomb is chief medical officer at Remedy Partners in Darien, Conn., and cofounder and past president of the Society of Hospital Medicine. Contact him at wfwhit@comcast. net. Ver the last 5 years, I've periodically devoted this column to providing updates to the Hospital Value-Based Purchasing program. HVBP launched in 2013 as a 5-year mixed upside/downside incentive program with mandatory participation for all U.S. acute care hospitals (critical access, acute inpatient rehabilitation, and long-term acute care hospitals are exempt). The program initially included process and patient experience measures. It later added measures for mortality, efficiency, and patient safety.

For the 2017 version of HVBP, the measures are allocated as follows: eight for patient experience, seven for patient safety (1 of which is a roll up of 11 claimsbased measures), three for process, and three for mortality. HVBP uses a budgetneutral funding approach with some winners and some losers but overall net zero spending on the program. It initially put hospitals at risk for 1% of their Medicare inpatient payments (in 2013), with a progressive increase to 2% by this year. HVBP has used a complex approach to determining incentives and penalties, rewarding either improvement or achievement, depending on the baseline performance of the hospital.

When HVBP was rolled out, it seemed like a big deal. Hospitals devoted resources to it. I contended that hospitalists should pay attention to its measures and work with their hospital quality department to promote high performance in the relevant measure domains. I emphasized that the program was good for hospitalists because it put dollars behind the quality improvement projects we had been working on for some time - projects to improve Hospital Consumer Assessment of Healthcare Providers and Systems scores; lower mortality; improve heart failure, heart attack, or pneumonia processes; and decrease hospital-acquired infections. For some perspective on dollars at stake, by this year, a 700-bed hospital has about \$3.4 million at risk in the program, and a 90-bed hospital has roughly \$250,000 at risk.

Has HVBP improved quality? Two studies looking at the early period of HVBP failed to show improvements in process or patient experience measures and demonstrated no change in mortality for heart failure, pneumonia, or heart attack.<sup>1,2</sup> Now that the program is in its 5th and final year, thanks to a recent study by Ryan et al., we have an idea if HVBP is associated with longer-term improvements in quality.<sup>3</sup>

In the study, Ryan et al. compared hospitals participating in HVBP with critical access hospitals, which are exempt from the program. The study yielded some disappointing, if not surprising, results. Improvements in process and patient experience measures for HVBP hospitals were no greater than those for the control group. HVBP was not associated with a significant reduction in mortality for heart failure or heart attack, but was associated with a mortality reduction for pneumonia. In sum, HVBP was not associated with improvements in process or patient experience, and was not associated with lower mortality, except in pneumonia.

As a program designed to incentivize better quality, where did HVBP go wrong? I believe HVBP simply had too many measures for the cognitive bandwidth of an individual or a team looking to improve quality. The total measure count for 2017 is 21! I submit that a hospitalist working to improve quality can keep top-of-mind one or two measures, possibly three at most. While others have postulated that the amount of money at risk is too small, I utilization, use of a certified electronic health record (hospitalists are exempt as they already use the hospital's EHR), and practice improvement activities.

It would be wise to learn from the shortcomings of HVBP. Namely, if MACRA keeps on its course to incentivize physicians using a complicated formula based on four domains and many more subdomains, it will repeat the mistakes of HVBP and – while creating more administrative burden – likely improve quality very little, if at all. Instead, MACRA should delineate a simple measure set representing improvement activities that physicians and teams can incorporate into their regular work flow without more time taken away from patient care.

The reality is that complicated payfor-performance programs divert limited available resources away from meaningful improvement activities in order to comply with onerous reporting requirements. As

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don't think that's the problem. Instead, my sense is that hospitalists and other members of the hospital team have quality improvement in their DNA and, regardless of the size of the financial incentives, will work to improve it as long as they have the right tools. Chief among these are good performance data and the time to focus on a finite number of projects.

What lessons can inform better design in the future? As of January 2017, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) – representing the biggest change in reimbursement in a generation – progressively exposes doctors and other professionals to upside/ downside incentives for quality, resource we gain a more nuanced understanding of how these programs work, policy makers should pay attention to the elements of "low-value" and "high-value" incentive systems and apply the "less is more" ethos of high-value care to the next generation of pay-for-performance programs.

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## New hospitalist unit has stellar patient satisfaction scores



Dr. Nelson has been working in clinical practice as a hospitalist since 1988. He is a cofounder and past president of the Society of Hospital Medicine and a principal in Nelson Flores Hospital Medicine Consultants. He is codirector for SHM's practice management courses. Contact him at john.nelson@nelsonflores. com. t's very unusual for hospitalists to achieve top quartile performance on the Physician Communication domain of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. This is the story of a group that did just that for patients on one unit of a large hospital.

I'm not sure how reproducible this would be at other hospitals, or even on other units in the same hospital, and wonder whether performance will stay at this remarkably high level much longer than the current 5-month track record of success. Even so, 5 months of success suggests they're on to something.

There is another hospitalist group at that hospital, but I'm discussing work done only by MedOne hospitalists, who together with hospital personnel, developed what they call the Comprehensive Medical Unit (CMU). Their goal was to involve multiple disciplines and use Lean principles to design a new approach to care on 5-Orange, a 20-bed unit in Ohio-Health's Riverside Methodist Hospital in Columbus. The CMU model went live in October 2016.

MedOne Hospital Physicians is a private hospitalist group of 35 physicians and 12 advanced practice clinicians, which comprise nurse practitioners (NPs) and physician assistants (PAs), constituting 46 full-time–equivalent clinical staffing. The group contracts with Riverside, which has approximately 710 staffed beds. MedOne also works in area skilled nursing facilities, helps a long-term acute care and rehabilitation hospital, and provides support to two other hospitals that are not part of OhioHealth.

#### Features of the model

At its core, this model is a variation of the increasingly common combination of geographically assigned hospitalists (who in this case don't have patients elsewhere in the hospital) and multidisciplinary rounds (that is, the physician and NP hospitalists make bedside rounds with a nurse and pharmacist). But their model also incorporates a few less-common features.

Only 4 of the 35 MedOne hospitalists are eligible to provide care on the CMU, and each still spends a significant portion of time in the regular hospitalist rotation working in the rest of the hospital. These doctors weren't selected as the highest performers or because they had the best patient satisfaction track record. Instead, five MedOne doctors volunteered to work on the unit, and four were chosen. A MedOne hospitalist NP also works on the unit, since any NP in the group is eligible to work there.

This is a hospitalist-only unit; patients who aren't assigned to a hospitalist are not placed on the unit. There is no deliberate attempt to assign patients to the unit based on how sick they are or how complicated their cases are. All are general medicine patients, including up to six intermediate care patients (for example, "ICU stepdown" patients requiring mask ventilation). While configured for 20 patients, the unit can accommodate as many as 24 patients and has done so numerous times. The hospitalists (physician and nurse practals. Physician Communication scores on the HCAHPS survey for hospitalists on other units at this hospital are in the bottom deciles, which is more typical for hospitalists.

Length of stay is half a day shorter than comparable units with similar readmission rates, and more patients are discharged earlier in the day. The four hospitalists who

I think the most notable outcome is the top quartile patient satisfaction scores from the 37 patients cared for on the unit who returned a survey, some of whom have asked to return to the CMU if they're hospitalized again. Specifically, 86% of responses were "top box," which places the hospitalists at the 84th percentile of performance for all hospitals.

titioner combined) have averaged 18.9 daily encounters since the CMU opened.

Nurse staffing on the unit was reconfigured to comprise bedside nurses – known as clinical nurses – and more experienced RNs – in the role of comprehensive charge nurses, who attend rounds and coordinate the patients' hospitalizations rather than doing bedside care. 5-Orange has one more charge nurse than is typical for other units in the hospital, so total RN-to-patient staffing levels and nurse staffing costs are higher. But the clinical nurses care for the same number of patients as do their counterparts in other hospital units.

In order to try to discharge patients early in the day, the NP sees only the patients who are being discharged, while the physician makes all other visits. When possible, I think it's best to minimize the number of times when a provider's first visit with a patient is also a discharge visit; this may increase the risk of misunderstandings and errors. Instead, in this model, the physician working on the CMU will already know the patient from the preceding days and will be on the unit and readily accessible to the NP all day, which might mitigate some of these concerns.

#### Outcomes

I think the most notable outcome is the top quartile patient satisfaction scores from the 37 patients cared for on the unit who returned a survey, some of whom have asked to return to the CMU if they're hospitalized again. Specifically, 86% of responses were "top box," which places the hospitalists at the 84th percentile of performance for all hospiwork on the unit report higher satisfaction, in part because they get an average of only 1 page a day – compared with the typical 15-40 pages their colleagues get working elsewhere in the hospital.

#### Cautions

I'm not sure why the MedOne model has yielded such impressive patient satisfaction and other results. While there are some relatively unique features of this model - only four hospitalists are eligible to work there and nursing roles have been reconfigured – I wouldn't expect these to yield such remarkable results. So far, the hospitalists on the CMU have roughly 5 months of data and just 37 returned patient satisfaction surveys, so it's possible that random variation and/or the Hawthorne effect are playing a meaningful role. It will be really informative to see their outcomes a year or 2 from now and to gauge how they fare if and when they implement the same model in other units of the hospital.

I suspect MedOne's precise configuration for staffing and roles of nurses, NPs, and physicians is important, but I'm guessing the most valuable thing they implemented was the creation of a powerful sense of teamwork and shared purpose among those working on the unit. The interpersonal bonding and feeling of shared purpose that likely occurred as they worked to devise and go live with the model, as well as the tremendous satisfaction at seeing their early results, have probably led to terrific enthusiasm within their team.

That enthusiasm may be the key ingredient contributing to their early success.